COMMENT ON:

STANDARDS FOR THE GROWING, HARVESTING, PACKING AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

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EXECUTIVE SUMMARY

It is quite surprising to see 1,000 illnesses a year associated with FDA outbreaks, due to multiple points of possible contamination, turned into an FDA estimate of 2.3 million illnesses a year, where the contamination "occurred on farm". It has no credibility.

Since this and similar manipulations of epidemiological data are the basis of the Analysis of Economic Impacts, and of the Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce (QAR), both these documents have no value as justifications for the proposed Produce Rule. The thousand pages of discussion and 70 pages of the rule also ignore explicit language in FSMA.

It is unfortunate to impose by regulation a generic E, coli indicator standard for water, compost and other inputs that is not correlated with the human pathogens of interest such as E. coli O157:H7, Salmonella enterica, Listeria monocytogenes, and the recent outbreak organism Cyclospora cayatenensis. Particularly when the on-farm consequences can be economically devastating -- at all scales of production.

The rule would allow sewage sludge to be used in both domestic production of produce and foreign imports. It maintains an ineffective seed treatment for sprouts while failing to regulate the production of seeds for sprouting. It ignores potential control points in CAFO's and animal production. In a larger context it ignores the selection and importation of increasingly dangerous pathogens from urban environments and intensive animal agriculture into crop farming ecosystems.

Fresh-cut produce, technically sophisticated and important as it may be, is a higher risk form of delivering produce to consumers. There are no kill steps, and there is always the possibility of cross-contamination; as well as pathogen survival, or even increase, in bagged product. Centralized processing can magnify the consequences. Yet fresh-cut is removed from the Produce Rule as a processed product, while it is not specifically covered in the new GMP for Facilities (Processing) rule. The FDA plays whack-a-mole with FSMA on fresh-cut.

Farmers are made to pay the price for others' failures and for systemic failure. The rule treats all food safety as the consequence of individual actions on a farm.

There are sufficient hazards to look at on-farm. But there is not a clear outbreak record saying planting to harvest has actually caused many outbreaks. How the FDA ended up in this position is part of the analysis. The short version is: all produce farms in the country are treated as part of HACCP for fresh-cut processing.

I present quite different views in some of the interviews reported, particularly from processors, but there are more points of agreement than expected. Two alternatives to the rule, one from a processor, are given at the end. They keep free choice, and free-market responses. Both are based on the necessity for research based ecological approaches to produce safety, the only option that has a chance of working long-term.

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INTRODUCTION

The proposed rule is a mess and a potential disaster.

It would misallocate both private and public resources, underutilize the FDA's actual strengths and capacities, damage most of agriculture in the United States with the exception of field crops, be a barrier to entry for all new farmers into our aging cohort of farmers, threaten ecologically based agriculture and the environment of rural America, and place extraordinary burdens on farms. At the same time, it fails to address some of the most significant food safety steps that could be taken, even within the limited framework of the produce rule. It fails to focus resources and regulation on the greatest opportunities for successfully reducing food safety hazards.

In this comment I will give an overview sketch of what I see as both a flawed structure and flawed content in the proposed Rule. The two types of flaws interact. I will also try to build the case for a different approach, given at the end, that could be considered as alternative means of regulating for improved food safety.

Preview of an alternative approach.

In my view, one should start with an analysis similar to HACCP but for the the entire farming system related to produce: not for individual produce commodities and not solely focused on individual farms. Finding a record of systemic outbreaks on a particular crop from a particular region, though, identifies a unique combined hazard, and the FDA letters and guidances in such cases often reflect this combined risk. The FDA's proposed rules, on the other hand, ignore this specific combined risk.

Washing post-harvest, in preparation for marketing, is one of the critical control points that can undue whatever prior food safety steps have been taken. It's counterintuitive that the very act of cosmetic preparation for sale to markets is, in fact, often not a safety benefit but one of the greater hazards in the production chain. Notice that this is a functional risk independent of commodity type, such as tomato or spinach or apple. The risk exists completely independently of who controls this function, whether farmer, handler or processor. In general, there is no benefit to even creating the category of mixed farm-facility if one uses a different overall approach.

It is an area where the FDA has shown expertise in identifying or stopping systemic risk in the past such as identifying persistent salmonella in ponds used as wash-water sources in whole fresh tomato production in the Southeast, and stopping such use; and identifying and showing facility and equipment contamination in cantaloupe washing operations during the Jensen Farms, 2011, pathogenic Listeria outbreak and investigation.

Its also one of the control points where I happen to agree that what happens on each farm is critical when the farm carries out that function of cosmetic produce washing.

Other control points are not even considered in the proposed Rule because it focuses solely on controlling each individual farm, rather than controlling persistent risks to the entire system. At least some major systemic off-farm risks, perhaps most of them, are also amenable to FDA regulation, Their control would both be more effective for produce safety and lessen the burden on individual farms.

For now, let produce washing control and regulation stand as an example of one of the many areas where the two different approaches appear to substantively agree and overlap in identifying a problem, while having opposing views on structuring regulation.

I. THE EPIDEMIOLOGY OF FARMING

A small change in coverage leads to a large change in analysis and content.

The subject of this section of the Food Safety and Modernization Act (FSMA) "Standards for Produce Safety" is farming: farm practices through harvest, of fruits and vegetables, while they are still raw agricultural commodities. The FDA is directed to prepare:

"...science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables...that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death." (First paragraph USC Title 21 section 350h Standards for Produce Safety).

In implementing the law however, this was expanded to "growing, harvesting, packing, and holding of produce for human consumption." (Title, proposed Rule). Yet the impacts on farming practices, narrowly defined, growing crops through harvest, and whether these impacts are justified, are the cause of most problems and controversy.

Covering the food safety issues of post-harvest steps on-farm, somewhere, is not controversial. Looking at overall produce safety, the act of washing fruits and vegetables can be a hazard point, as can the use of cooling water and other post-harvest preparations for shipment. Covering packing and trimming directly from the field at harvest is also, in my view, non-controversial. The post-harvest steps need to be covered somewhere under the FSMA and the only other place they could be covered is the Facilities Rule (Current GMP Practice and Hazard Analysis for Risk-based Preventive Controls for Human Food) for food processors, so farmers should be better off when these particular post-harvest steps, when under farm control, can be covered under the Produce rule.

It seems innocent, a technical issue of where different aspects of produce safety fit in the five proposed Rules. Flawed technical decisions will also turn out to be important, later on.

The controversy starts right here, however, because throughout the documents created to support the proposed rule, post-harvest food safety issues are used to justify control of farming practices.

Eventually even retail contamination of produce is used to justify on-farm regulation through mis-representing epidemiological data and statistics. The extension of the law's field of coverage ends up not looking very innocent, in context. It was the first step in an un-warranted path of choices.

In many cases the FDA chose badly. They used a flawed analysis to support these choices. This analysis depends critically on confusing and confounding data on hazards that occur on-farm, from planting to harvest, with post-harvest hazards on or off farm, then with hazards that occur always off-farm, and finally with hazards that occur temporally and spatially later in the chain of production.

Farming-caused outbreak data

The record of proven on-farm causation of outbreaks is remarkably thin for such an extensive set of regulations of farming practices, the actual subject in FSMA for the Rule**.** Consequently the FDA goes to considerable lengths to justify regulating farming practices without data that would directly justify such regulation.

This is a crucial point so it deserves a little more discussion. Even when one adds in highly probable farm sources there are relatively few U.S. cases -- a half a dozen to a dozen being generous? It depends on the criteria. I know of one case that I consider bulletproof, from 2011 (Washington County, Oregon, O157:H7 on strawberries) yet no data after 2010 were used for developing the Rule and this case does not appear to be discussed. (At the end of the next sub-section I relax the criteria to imagine all the FDA listed produce outbreaks are farm-caused. The data are still grossly mis-used in the analysis for the proposed Rule).

I see an ample discussion in the Prologue to the Rule of a famous pathogenic Listeria case, from Nova Scotia in 1981, both geographically and temporally outside the (varying) data sets used to justify the proposed regulations.

Both of these cases, if they had occurred in the United States during the time frame(s) used for analyzing outbreak data, could have been handled under the general FD&C statutes and regulations, without FSMA at all, by saying:

Do not harvest produce directly expose to excrement.

In the Nova Scotia case this could be explicitly stated as: do not harvest produce directly exposed to excrement when two of the sheep in the flock responsible for said excrement *just died of listeriosis.*

Cabbage was the produce grown on the Nova Scotia farm. It was processed into coleslaw, raw shredded cabbage without a kill step. This was the original case that led to the recognition of any food as a vehicle for Listeria transmission. (Can J Infect Dis Med Microbiol. 2008 September; 19(5): 327–328).

In my interview with EB Farms, they mentioned there are at least two cases when their private traceback of rejected lots did find a farm source of contamination. One was a farm input (compost) and another was due to an on-farm water system contamination through a cross-connection. There were seven tracebacks in total which found a causal source out of 1,000 trace-backs of rejected lots. This is private data, not part of the rule-making data, and brings the "certain" farming practices cases up to three, two of which did no harm, but might have in the absence of a test and hold program, and other controls, at the processing plant.

The extent of many outbreaks and their severity (their magnification and damage) are often known to be caused by post-farming practices in a processing facility. Processing conditions can contaminate an entire production batch, particularly a problem for fresh-cut produce, where: there is no kill-step; damaging plant tissue, a major risk, is part of the actual preparation for market; packaging can maintain or allow increase of pathogens in a contained environment; and time to consumption may take weeks.

When severity and extent of an outbreak is caused by processing conditions, not all of the responsibility for outbreak damage can be placed on farming practices. The strict liability for contamination, one of the measures of responsibility, actually stays entirely with the processor and holder of a brand sold into the market (Marler CPS 2013).

There also has been a systemic bias in outbreak investigations and reports to find exculpatory excuses for processors. This goes all the way back to the first reports of O157:H7 in apple juice from the early 1990's. A more detailed discussion of how this affects assigning contamination to farming can be found in Appendix A to this comment.

Mis-using CDC and FDA data to justify on-farm regulation.

The main documents supporting the proposed rule are the QAR (Qualitative Assessment of Risk) the Economic Analysis (Analysis of Economic Impacts) and the long prologue before the actual proposed Rule (the "Prologue" which is 475 pages long; the rule itself is covered in 73 pages). These in turn are supported mostly by on the December 13, 2011 DHHS "Memorandum to File" by D'lima and Vierk, and by the analysis in Appendix A of the Economic Analysis. All of these rely on CDC epidemiological data tables although they use different data sets and years of coverage between the supporting reports, and are using subsets of CDC data for "FDA regulated produce" outbreaks".

The Memorandum to the File is relatively straightforward, reporting on 131 produce outbreaks from 1996 - 2010; those not likely due to contamination at retail or home

settings along with their associated illnesses, hospitalizations or deaths. The 131 outbreaks caused 14,132 illnesses 1,360 hospitalizations and 27 deaths. On-farm contamination causing damages has to be a smaller subset of these numbers, no matter which methodology one uses to assign responsibility for contamination. Some are due to failures in fresh-cut processing, some due to lack of cold chain in transportation, some due to failure to to control pathogenic Listeria when there was a cold chain, some due to contamination of wash water for cosmetic preparation for market; some due to failure to monitor sanitation of flume or wash water in handling and processing.

The numbers of outbreaks and health consequences due to U.S. causes, including U.S. farmers, can be significantly reduced by removing known foreign-sourced outbreaks, and perhaps adding in the unknown sources where there was not a domestic source in the database (Cyclospora for example).

The only problem I see with the Memorandum is they fail to account for the problems in fresh-cut statistics: neither the CDC nor the FDA really began identifying "fresh-cut" as a separate note until after 2002 (See Cohen 2008 and Appendix A of this Comment). The fresh-cut data are therefore biased lower and the whole produce data correspondingly higher. We will return to this later, but for now will set it aside.

Yet the QAR, the Economic Analysis and the Prologue all repeat versions of the following, basing an analysis from just the 5 years 2003 to 2008 (probably a good choice) they come up with the following ***annual*** illness amounts:

"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."

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

It almost doesn't matter how they did their calculations, or their alternative methodology which was closer to 1 million instead of 2.3 million (which they didn't use); that sometimes they include fresh-cut and sprouts or exclude them inconsistently.

They turned less than 1,000 illnesses a year due to "FDA regulated" raw agricultural commodities into 2.3 million estimated annual illnesses due to the same RAC's, a 2.3 thousand fold increase (Table 17).

Then they attribute all these illnesses as “caused by microbial contamination of produce commodities where the contamination occurred on farm” without a shred of analysis or even discussion.

These are the fictional statistics and fictional attributions of cause used as the basis for the entire economic analysis of the proposed rules costs and benefits, which in the end are real costs to farmers and fictional benefits to consumers. (See Appendix B).

This means the entire economic analysis, in all its detail and glory, is totally worthless. The proposed Rule should be thrown out on this basis alone.

A sketch of how it gets worse.

If one wants a golden thread to follow through the CDC epidemiology and through the analysis, one can use norovirus reports. No norovirus outbreak has been traced to on-farm contamination. Some of the CDC epidemiologists may be unhappy about this [see: Epidemiology of Foodborne Norovirus Outbreaks, United States, 2001–2008, Hall et al., Emerging Infectious Diseases , Vol. 18, No. 10, October 2012], and it may change with better technology in the future but that is the status of CDC data through 2011. For all of the illnesses covered and reported throughout any of the time periods used in analyzing the proposed rule nearly all norovirus outbreaks can only be attributed to food handling at retail or in the home and none are known to be on-farm caused.

Norovirus outbreaks play a huge role in total illness numbers. They also can be used as a surrogate statistic that tells one the minimum percentage of reported illnesses NOT due to farming, on-farm contamination post harvest or anywhere in the chain of production until food preparation for consumption (Fresh-cut, not considered a RAC in the proposed rule, would be an interesting place to look for norovirus because it is a kind of centralized food service from processors). Norovirus should never show up in any statistical analysis linking farming to outbreak illnesses, based on actual data up until now.

Instead the economic analysis worries about under-reporting of norovirus because it usually has such “mild” symptoms. And they manage to attribute norovirus illnesses to “FDA cases” “CDC cases” and “Estimated Illnesses Attributed to FDA Products” as if these were related to putative farm-caused produce outbreaks instead of retail, foodservice and home preparation (for example Table 138, Appendix A, Economic Analysis, page 371).

In general, each support document parses carefully or carelessly to imply foodservice data and analysis being discussed is farming data. They have to be read with lawyerly attention to detail and context because the contexts keep switching.

The FDA made some bad choices here. Why were these choices made? It could be that they have to puff up the numbers with estimated unreported illnesses, and to assign

them without analysis as farming-caused, in order to economically justify the proposed rule. Maybe they were fixing the analysis to fit an already decided-on conclusion. I return briefly to this subject at the end of the Comment, but anyway you look at it, it's a disaster.

II. PESTICIDES, HEAVY METALS AND RADIOLOGICAL MATERIALS

There is clear language in FSMA that the proposed rule should cover radiological, chemical and other non-biological hazards as well as considering protections against deliberate acts of contamination. Examples of why pesticides, heavy metals and radiological materials should be covered in the Rule can be found in Appendix B, as well as a discussion of the impact on **urban farming**.

It is traditional to follow the black-letter law when writing regulations, although this does not always happen. FSMA has a complex set of regulations where the five proposed Rules need to articulate with each other, and also has to cross-connect with separate laws for the EPA, the USDA regulation of animals, the Organic Foods Act, the Bioterrorism Act and others. For example there are overlaps in worker hygiene facilities with OSHA and other regulations.

At a minimum each Rule under FSMA should have sufficient content to provide a clear legal nexus with overlapping rules and regulations. There should also be substantive consideration of non-biological hazards. The Produce Rule dismisses the need to follow the letter of the law in a one line footnote to the QAR and a Memorandum for the Record (May 29, 2012) which seems off-point. (see appendix B)

It seems to me that the FDA has missed the increased importance of urban agriculture and urban farming across the country as a substantive new area to consider for at least a linked Guidance under the Produce Rule.

The FDA also failed to consider not just the contamination of urban properties used for growing produce, but also the massive contamination of agricultural lands in other countries which may ship produce here under the same or equivalent Produce Rule. (see Appendix C to the comment).

Let me pull all these issues together with a discussion of sewage sludge, considered here as a source of heavy metal contamination and in a later section of the Comment as a biological hazard.

No one I know of in the U.S. chain of production, from farm to fork, is asking for sewage sludge to be used in produce production. *The simplest rule would be to ban sewage sludge use in produce, following the Organic Farming Act's rules.*

Instead, the proposed Rule relies entirely on the fact that the EPA has a standard for microbial pathogens, should sewage sludge ever be used. The EPA is not recommending such use. The proposed rule entirely ignores the EPA-determined issues of heavy metals in sewage sludge -- such as copper -- and pesticide and pesticide breakdown residues, because the proposed Rule takes the position that heavy metals and pesticides are not an issue for produce safety under the Rule. The fact that the EPA restricts the use of sewage sludges for produce to Class A sewage sludge, the cream of the crop, so to speak, and further restricts the timing and use of even Class A materials, because of heavy metals, is entirely ignored.

The FDA has also opened the gates for the importation of produce grown with sewage sludge from anywhere in the world.

Finally, let me mention that if the Produce rule could create a nexus with other laws covering deliberate acts of contamination, it could lead to farmers being paid for pathogen monitoring of water. (see Appendix D to the comment).

III. AN IRRIGATION WATER STANDARD THAT DOES NOT CORRELATE WITH HUMAN PATHOGENS.

The generic E. coli standard for irrigation water will probably receive a great deal of criticism, as will the the action levels set by using a recreational water standard for swimmers to avoid gastrointestinal illness. I will treat the main objections briefly and then look more closely at how they came about in the nest section.

The basic objection to using generic E. coli as an indicator is that it is un-correlated with the human pathogens of interest for produce production: specifically STEC E. coli including O157:H7 and salmonella. (I actually have not seen anything about the relationship with cryptosporidium or hepatitis A.) There is a growing literature on how this standard is specifically inappropriate for produce production, particularly leafy greens, including by USDA researchers. (See: January 3, 2011 Shelton, D.R., Karns, J.S., Coppock, C.R., Patel, J.R., Sharma, M., Pachepsky, Y.A. 2011. Comparison of generic E. coli vs. pathogenic E. coli virulence factors in an agricultural watershed: implications for irrigation water standards and leafy green commodities. Journal of Food Protection. 74:18-23.).

Will Daniels told me that a very large set of comprehensive data on this is being prepared by Earthbound Farm, one of the major fresh-cut producers in California, using results from 6 years of constant product and environmental testing (see EB Farm interview). They test for human pathogens directly as well as testing for generic E. coli as members of the California Leafy Green Handlers Marketing Agreement (CA LGMA). His view, based on experience and data, is that testing must be done for the human pathogens.

My impression is that while this data confirms the need for specific human pathogen testing in processing without a kill step (fresh-cut production),a lack of correlation with human pathogens also implies that the generic E. coli standard is a completely inappropriate indicator to set up as national policy, used throughout the United States for all fresh produce, particularly for irrigation water.

Use of this standard is defended in the proposed Rule's supporting documents by reference to the CA LGMA and similar programs. Briefly, in my view this standard was ripped uncritically from a different context, where it actually makes some economic and quality control sense, and placed in the proposed Rule, where it makes no sense at all.

Here is part of Trevor Suslow's summary in an Issue Brief for the Pew Charitable Trust's Produce Safety Project (Standards for Irrigation and Foliar Contact Water):

"A limited, and arguably outdated, set of indicators of fecal contamination has been used by the fresh produce industry to assess the suitability of water used in preharvest crop production up to the point of harvest. Many regional GAP and CSG systems have relatively recently adopted EPA recreational water quality criteria for establishing action thresholds, in the absence of actual risk-based data based on irrigation water (CSFSGLLGSC 2006 updated 2009). As internal and external pressure is exerted for national standards, a simple approach has been to adopt these EPA criteria." (page 6, Pew Issue Brief)

"The EPA criteria, as they were not intended to apply to risks associated with irrigation management of edible crops, do not take into account the kinetics of die-off during post-irrigation intervals and exposure to environmental stresses associated with crop production." (page 7)

"...for individual growers or regionally among growers along a common irrigation source or system, hitting a single sample value above the strict threshold, for example 235 MPN/100 ml for overhead irrigation, is a critical event. Avoidance of hitting these meaningless breakpoints, relative to actual risk, invites temptation towards unethical practices." (page 8)

Multiple sources discuss the lack of correlation with human pathogens and the specific lack of suitability of generic E. coli for monitoring inputs for produce safety.

IV. WHAT HAPPENS IN SALINAS SHOULD STAY IN SALINAS

The CA LGMA greatly influenced the Arizona LGMA (AZ LGMA) and similar programs on tomato production in Florida, and fresh produce production in British Columbia as well as the standards in the proposed Rule. (Economic Impact Analysis pp 222 and 392).

Four of my interviews were with people with extensive experience with produce production in California; with production in the Salinas Valley, the "salad bowl of the United States" in particular; and with the CA LGMA. Scott Horsfall is Executive Director of the CA LGMA (LGMA Interview). Will Daniels is VP for Quality, Food Safety and Organic Integrity for Earthbound Farm (a major processor), and a long time board member of the CA LGMA; Samantha Cabaluna is VP of Communications and Marketing for Earthbound Farm (Earthbound Farm Interview). Jo Ann Baumgartner runs the Wild Farm Alliance and has the most experience and information on environmental consequences (Wild Farm Alliance Interview). David Runsten is Policy Director at the Community Alliance with Family Farms (CAFF Interview).

The CA LGMA was formed following the 2006 E. coli O157:H7 spinach crisis, under the triple pressure of restoring market confidence in spinach and other leafy greens, an FDA that clearly expressed it had lost patience, and in effect told the produce industry "fix this or we will fix it for you" (see Appendix E), and major buyers who were imposing their own private standards on production, with or without evidence for whether their demands increased actual food safety.

Much of what the LGMA did to impose standards on production, including choice of a water quality testing standard, made more sense in that context. They had to make their best estimates of what standards would actually improve produce safety, while mollifying the major buyers, and showing the FDA that the safety problems were being effectively worked on.

They knew that the generic E. coli standard was not perfect, but the other indicators were worse: generic E. coli was the least bad of the choices that were available at the time. In general, the LGMA's metrics and rules are stricter on growers than the proposed Rule would be for water quality and other metrics of food safety. Will Daniels, an LGMA Board member, would like to see them change over to specific pathogen testing in the LGMA metrics. Growers who produce for Earthbound have to do specific pathogen testing, separate from the LGMA rules.

I did ask Scott Horsfall whether there had been any studies on the effectiveness of the LGMA in improving food safety; for example comparing equal numbers of years before and after the LGMA's formation, and the numbers on recalls and outbreaks. Those studies have not been done. My naive expectation was that this would have been a question their many visitors from the FDA, including some writing the proposed rule, would have asked, before using the CA LGMA as one of the models for produce safety.

A critical review of The LGMA's effectiveness -- at least in its own context -- would be a key procedure in a scientific assessment.

I also asked how one would go about separating out the effectiveness of the LGMA by itself, when there had been concurrent improvements in food safety procedures by the major processors in California, as well as continued additional metrics required by different buyers, or processors such as Earthbound Farm. It would be difficult to do, but this also should have been looked at before using the LGMA as a model.

The LGMA and the associated changes demanded by buyers have been costly for both growers and the farm environment. Dave Runsten told me about even large growers who were unhappy about some metrics which did not appear to be based on any valid science, and about the fact that the growers end up bearing the costs for food safety improvement, but no one else wants to pay for it. He also describes the problems of using rules designed for the largest growers, when they are applied to different sized farms. Jim Prevor has been writing for years about the reluctance to actually pay for food safety on the buyers side of the produce industry, including in a recent July column of The Perishable Pundit (parts of which are reprinted here in the Interview section, with his permission). Jo Ann Baumgartner briefly describes the environmental destruction that happened in Salinas under the combined pressures from buyers and the LGMA.

Should similar changes to those that happened in the Salinas Valley really be imposed on all farmers in the nation? Scott Horsfall's comment was that the LGMA was designed for lettuce and leafy greens produced in California, and seemed to be working as part of a co-ordinated or layered set of efforts, for this region and these crops. They do not know what will work for other regions and crops.

Here is my assessment, and it won't make anyone happy. The generic for E. coli irrigation water standard has some utility as part of the LGMA in the Salinas Valley and elsewhere in California, because of the overall context and not because it can be used to detect human pathogens. That context includes separate buyer and processor requirements for specific human pathogen testing. An example is the Earthbound Farm (processor) program, which we know about because they disclose it. Other contracts are private or confidential but not disclosed. Processing and handling in California is consolidated to a few major companies, and they have been through the food safety wars, and made significant improvement in their own safety operations which are actually not covered by the LGMA; it does not cover processor or handler operations.

In this specific context a generic for E. coli standard adds a kind of useful non-random sampling, By this I mean specifically that the highest levels of counts, as they go significantly and repeatedly over the EPA 503 or WHO limits, are indicators of significant problems that also have to be dealt with and corrected, as Brinton found for systemic risk (including for O157:H7) when sampling and testing compost. Generic E. coli can also be an early warning indication that water quality is changing.

Outside that context, I wonder if the LGMA and similar programs create a kind of moral hazard for processors or handlers who have not been through the same history as the California processors and handlers, and may not know about the extra steps needed for food safety particularly for fresh-cut and similar products.

If I were an onion grower in the Lower Snake River Watershed of Oregon and Idaho, or a Southeast onion producer from Georgia and neighboring States, it would be hard to accept being forced out of production because of irrigation water standards developed in this manner, for a quite different commodity used in a higher risk food category (fresh-cut). Used as a national standard in the proposed Rule, the generic E. coli standard for irrigation water, and perhaps other metrics, do not seem to be developed for food safety.

They seem to be developed for food security theater.

V. PARADOXES IN MANURES, COMPOSTS AND SEWAGE SLUDGE

There is an inherent contradiction, in the rationales for the proposed Rule, in treatment of animal manures and human excrement.

They are forced to consider composting as a valid safety process by FSMA, but do not like it. Really the only manures they consider safe have been chemically or physically sterilized at great expense. But sterilized manures, they recognize, are a completely open nutrient petri-dish for subsequent contamination by human pathogens, without any inherent soil-microbial control. Sterilizing itself creates a new hazard. Really, not even sterilized manures or compost are safe.

At the same time EPA 503 sludge, and composted human sewage sludges (with or without sewage solids) are given a complete pass for produce use as adequately regulated and produced, without any studies or equal concern for adequacy of processing as commercial products. Yet if the sludges have, in fact been adequately treated to be human pathogen free, which generic indicators do not measure, they also would be a petri-dish of nutrients, open for re-contamination like sterilized manure or composts.

They seem to ignore the human pathogen status of urban greenwaste composts and other sources of contamination (see below).

The animal sources of human pathogens in manures are, naturally, from concentrated sources for economic reasons and are CAFOs (concentrated animal feeding operations). But CAFO's are not touched by the proposed Rule despite being a major contributing source of increasingly virulent and robust human pathogens entering farms and the farm environment, and quite possibly the most important source.

One of the common illusions about animal manures and manure based compost use in the United States is that they are predominantly used in organic farming.

Organic farming has only slowly increased in the United States, and is still a small % of total farmland or production. Cover cropping with nitrogen-fixing legumes is a common alternative source of nitrogen in organic production. Most farm use of both inputs have been, and continue to, be in conventional farming. In his interview statement, Dave Runsten, in his interview statement, mentions the concern that dairy manure, brought in by conventional produce growers from the San Joaquin Valley years ago, may have been the source of introducing emerging pathogens like O157:H7 into the Salinas Valley farm environment, where they may persist. Tree crops growers have "learned from the organic growers" to use compost for long term soil improvement and water retention. Spikes in petroleum prices cause spikes in nitrogen fertilizer prices making animal sources of nitrogen more economically attractive to conventional growers, who have a choice between biological and chemical fertilizers.

While organic growers have long had rules and regulations to protect against human pathogens in manures and composts, now part of the law for organic farming, conventional growers have not had to follow the same rules and protective practices. The result is that animal manure and composts used in conventional agriculture are often a greater hazard than the same manures, used under more protective rules and regulations, in organic agriculture.

A second common illusion is that human pathogens are more likely to be found in manure composts and that green-waste composts -- used increasingly to reduce land-fill disposal -- are "safe". **Appendix F** discusses William Brintons work sampling commercial greenwaste composts from three west coast states and comparing both fecal indicators and specific pathogens including E. coli O157:H7 and salmonella. It is fairly depressing reading, including the finding of O157:H7 at major California commercial greenwaste composting operations, situated "within important vegetable producing regions" 2 years after the 2006 spinach outbreak.

One finding that may be useful for quality control and possibly regulation, with further study on the specific human pathogen results, was that:

"A useful distinction was observed when applying the voluntary
California Maturity Index method for compost classification.
Samples that did not meet the basic test requirement
had a significantly higher E. coli content than did
those that met the requirement (P 0.01)."

The four systemic entry points of human pathogens into the farm environment are: CAFO's, urban waste including greenwaste,, human medical waste or illness, and persistence in the larger environment after introduction. Persistence may be secondary and derived from the other three introduction points. It is hard to measure over time because of constant re-introduction of human pathogens. One can at least aim to stop

the introduction of new, worse, pathogens which can in turn become persistent, and vectored by a variety of means.

The proposed Rule is a perfect opportunity for letting the free market respond to increase food safety, by regulating the human pathogen status of farm inputs derived from CAFO's (and urban waste), which backs up to their pathogen status before they enter products for farms or the farm environment. This is completely absent as even a topic in the Rule.

If one looked at animal production, comparing fresh weight of meat (or milk for dairy) with fresh weight of feces and urine, one might conclude that food is the by-product. Animal producers can treat human pathogen status of manure as an economic externality currently. If there were a cost to the human pathogen status of manure, as there is a cost, for example, to the human pathogen status of sold meat, particularly O157:H7, animal producers would respond as quickly as they could -- by a variety of increasingly sophisticated and lower-cost means -- to achieve lower human pathogen status, or human pathogen-free status, for manures.

Getting full price for manure going into composting, for example, should depend on the pathogen status of that manure before composting begins, because it will require much more attention and control to produce a safe product to sell to farms.

A simple regulation would require testing for status of human pathogens for manure and greenwaste before use and require greater processing controls and testing requirements for composting depending on the original status of the source material. At a later stage, require testing for human pathogens on all composts or biological inputs before they can be sold to farmers.

If one wanted to significantly increase food safety with minimal regulatory change, a straight-forward way to do it would be to say: all manure and manure based compost use must meet or exceed the standards for their use in the Organic Foods Act". This is part of my alternative to the proposed Rule at the end, with some qualification.

But I advocate for the simplest possible regulation that has the greatest statistical effect for increasing produce safety overall, and where the FDA has the greatest expertise and possibility of being effective. The proposed Rule, on the other hand, is based on treating each farm like an independent facility whose every action should be specified. It over burdens farms because of factors beyond their control, while missing the opportunity to control those systemic factors using the tools, imperfect as they are, available to the FDA under FSMA. (see appendix E)

VI. DEPRAVED INDIFFERENCE IN SPROUT REGULATION

Seeds used in sprout production should be grown for sprout production. It's pretty basic.

This is the single most useful regulation that could be implemented for sprout production. The produce Rule should require that any seeds used for sprout production

be grown for sprout production; and grown and handled according to a Guidance produced by the FDA in consultation with others.

If the sprout industry cannot obtain seeds they need produced in this manner for a particular crop or variety, they should cease production of that crop or variety. Seed treatments knock down pathogen numbers; pathogens can recover high numbers during sprout production.

Here is the coverage of seeds for sprouts under the proposed rule:

"Subpart M--Standards Directed to Sprouts
§ 112.141 What requirements apply to seeds or beans used to grow sprouts?
In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.
(a) If your farm grows seeds or beans for use to grow sprouts, you must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.
(b) If you know or have reason to believe that a lot of seeds or beans have been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts.
(c) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards."

And here is the New York State definition of depraved indifference:

"N.Y. PEN. LAW § 125.25 : NY Code - Section 125.25: Murder in the second degree

2. Under circumstances evincing a depraved indifference to human life, he recklessly engages in conduct which creates a grave risk of death to another person, and thereby causes the death of another person."

Using seeds for sprouts that were produced for completely different circumstances, were not grown with human safety in mind, and using them in a known very high risk production system seems like reckless conduct to me.

Perhaps failing to regulate one of the greatest known hazards is another example of reckless conduct.

The problem is long-standing. Sprout producers use an increasingly complex mix of crop seeds for sprouting. In Germany, before the Hamburg-centered major O104:H4 outbreak that swamped their country's medical system, an entire cuisine of unusual sprouts for flavoring salads had been developed, including using fenugreek seeds, the cause of the outbreak, for a curry-like flavor.

From the beginning of commercial sprouting the industry has used some seeds developed and sold for rangelands and forage production, not for human food use. By their intent to use as sprouting seed,a planting seed lot somehow becomes transformed into a human food. In the beginnings of the industry, even issues of chemical seed treatment were neglected, such as fungicides and other seed protectants, leading to problems at the consumer level. A planting seed lot could have been grown in Australia,

a major producer of range and forage seeds, on land grazed by cattle, harvested from windrows on the ground. A seed lot could be alfalfa or clover seed grown under similar conditions in the U.S. for that matter.

There have been successful tracebacks from sprout outbreaks to seed lots for over 15 years now. There are very few factors to control in sprout production in enclosed facilities: seeds, water and equipment. This is a sterilizable contained environment unlike farmland. There is no complex ecosystem in sprout production, so it should be a model case for the success of a sterile approach to agriculture.

Instead, the record is the opposite. FDA regulation has failed for one of the most controlled production systems imaginable in "agriculture" and failed continuously under increasingly harsh guidances. Some outbreaks, recalls and warnings are due to facilities contamination, separate from seed issues. In general the recommendations are for harsh chlorine treatment of seeds before sprouting, which can be completely ineffective as log counts increase during sprouting, and for rinse water testing, which makes complete sense because it samples the pathogen-status of the entire production lot in a drum sprouter.

My impression is that the surviving sprout producers in the United States have paid increasing attention to starting with clean seed sources over time.

The origins of the 20,000 ppm chlorine treatment are apparently from a study that did not intend such an industrial use. It represents a worker health and environmental disposal hazard. Fransisca et. al found

"The seed sanitation treatment with 20000 ppm chlorine solution that is currently used by the sprout industry was once again found to be ineffective in eliminating inoculated pathogenic cells. More importantly, the remaining cells that have survived the chlorine wash would grow during sprouting to reach an alarmingly high cell concentration….

"...The SEM microimages showed that the bacteria were mostly located in the roots of the radish sprouts and all across the seed surface. The *E. coli* O157:H7 87–23 cells appeared to be located in biofilms or embedded into the radish sprout tissues during sprouting."

and noted the greater effectiveness of a .02% calcinated calcium spray in keeping bacterial counts down after sprouting.

[Journal of Food Science, 76: M404–M412. doi: 10.1111/j.1750-3841.2011.02270.x]

There is an active literature on alternative control methods of pathogens artificially innoculated on seeds. Success depends on pathogen load, seed type and pathogen. For example, Studer et al. eliminated high levels of inoculation of two STEC E. coli and a Salmonella enterica serovar on alfalfa and mung beans using aerated steam; they could not eliminate the Listeria monocytogenes strain used (but had 5, and 4 log reductions.[Appl Environ Microbiol. 2013 Aug;79(15):4613-9. doi: 10.1128/AEM.00443-13. Epub 2013 May 24.]

Starting with the cleanest possible grown and delivered seeds has obvious benefits.

Issues from sprout production shade over into fresh-cut and leafy green production. Will Daniels at Earthbound Farms had all seed lots tested for human pathogens before planting due to problems he saw in sprout production with seeds. After five years worth of data were negative, this was relaxed. Internalization of human pathogens in plant tissue was an issue was first demonstrated in Japan for growing radish seedlings following the Sakai City July 1996 outbreaks (over 10,000 persons affected).

Although pathogen concentrations used were quite high, this demonstration of the possibility of internalization has led to a continuous research program ever since, including concerns about internalization from contaminated irrigation water, either all the way from the roots to tomato fruits, or through blossom infection by human pathogens carried on water droplets (FDA and USDA, Zheng et al. 2013, Colonization and Internalization of Salmonella enterica in Tomato Plants. Appl Environ Microbiol. 2013 Apr;79(8):2494-502. doi: 10.1128/AEM.03704-12. Epub 2013 Feb 1.).

These experimental contamination experiments still use very high concentrations of pathogens above log 8, (10 to the 8th power) cells per milliliter. This is quite a turbid looking concentration. Such studies are oriented towards showing the plausibility of irrigation water -- even drip irrigation -- being a potential route of contamination from persistently contaminated ponds used as an irrigation, through the roots and possibly affecting fruits; similarly blossom studies consider rain splash dispersal to flowers.

The question is: what significance do such experimental inoculation studies have on farms? Is a possible route a probable route? Some epidemiological studies seem to assume this is a given (possibility = probable or likely cause of contamination).

For the sprout discussion let us look at a different observation in Zheng et al.'s recent paper:

"...methyl bromide has had a long history of use in tomato cultivation as a soil fumigant in the eastern United States, and recent metagenomic studies have shown that such practices have diminished overall soil microbial diversity (28), perhaps increasing the potential for Salmonella colonization and persistence in the soil. Taken together, these findings support a hypothesis whereby Salmonella might be introduced in the soil via potentially contaminated irrigation water....During the transplantation stage, a tomato plant is more susceptible to internalization, thereby increasing the occurrence of Salmonella internalization in the plant, and, subsequently, causing an increased risk of Salmonella contamination of preharvest tomato fruits."

They ask the key question: does an impoverished soil microbial ecosystem (after sterilization) make a more open niche for colonization by a human pathogen of the rhizosphere? SImilar questions could be asked for compost, water and other sub-ecosystems.

I think some of the answer can be given from comparing three kinds of production systems: (1) building contained drum-grown sprouts grown under attempted aseptic conditions but with frequently contaminated seeds, air and sunlight and soil ecosystem exposed micro-vegetables (I suppose these could be called really-baby vegetables), and baby vegetables grown for fresh-cut in intensive farm production. Some microvegetable producers use smaller versions of the farm harvesting equipment used in large-scale baby greens production.

The great increase in food safety seems to come between sprout production and microvegetable production. To me this suggests that research on contaminated seeds used in four systems (1) sterile drum production, (2) grown in soils with complex microbial ecosystems versus (3) the same soils after being autoclaved, (4) grown in the unsterilized soil in open conditions for microvegetables, could tell us a lot about the relative roles of seeds and soil microbial ecosystems in food safety, with implications beyond sprouts.

The FDA asked for comment about the relative safety of drum production of sprouts vs tray production and growth in soils. My impression is that normal sprout production in drums, with no ecological beneficial microorganisms, is an ideal system for spreading contamination. Whether soil and tray grown sprouts are actually safer or just less ideal is an open question. I have not compared sprout production to mushroom production.

Another area to research is a kill step during sprout growth, when human pathogens are fully exposed to treatment rather than still protected by seed coats and other niches in the seeds and early sprouts. It has to be a treatment that seedlings (sprouts) can survive but pathogens cannot. Very dilute calcium oxide solution was one possibility. It is possible that a dilute ethanol bath and rinse, even diluted wines, would work. I hesitate to recommend phage mixtures, here and in fresh-cut, because their routine use should simply lead to selection for phage resistance, particularly under rapid growth conditions. Phage can also transfer virulence and antibiotic resistance, so quality control is a major issue.

VII. MORAL HAZARD AND THE FRESH-CUT PROCESSOR

I interviewed one California processor (EB Farm) and one CA representative of a processor/handler produce safety program (CA LGMA). Both were relatively positive about the proposed Produce Rule, and about how the Produce Rule interlocks with the Facilities Rule, with some caveats. Will Daniels from EB Farm was explicit about fresh-cut having unique hazards as fresh processing without a kill step. The extraordinary steps EB takes to compensate for this increased hazard can be found sketched in the EB interview. However, he opposed the concept of separate specific regulations for fresh-cut processing and fresh-cut farming. In this section I contrast more recent experiences that differ between California processors and others, that indicate the need for both kinds of specific regulation.

The hypothesis is simple: once burned or sued, twice shy. The necessity for a layered, complex set of safety steps should be clearer to everyone in a processing operation.

I briefly reviewed the precautionary recalls and warnings of major California fresh bagged and fresh-cut-bagged processors by the FDA for 2012. Often these were initiated by information from State random sampling programs and I do not know to what extent these programs, or anyone, sample institutional fresh-cut wholesale production. The companies were Tanimura and Antle, Dole, Chiquita Fresh Express, Ocean Mist, Taylor Farms, and Earthbound Farm. Sometimes these companies are the processor, and sometimes they are the brand being recalled because another processor toll-processed for their brand.

Three trends stand out for California: increased dominance of Listeria monocytogenes as the pathogen of concern, increasingly complex mixtures, where non-leafy-greens are the source of the contamination across a wide range of brands (Gills Onions LLC, chopped onions with Listeria; salmonella in Sunland peanuts), reduced numbers of salmonella or O157:H7 recalls due to leafy greens and an absence of outbreaks. There were recalls associated with O157:H7 and salmonella. Except for whole bunched cilantro, correctly identified as high-risk in the documentation for the proposed Rule, most of the recalls seem associated with post-farm conditions at processing.

The complexity of the recalled product seems to be an extension of what I used to call “food service from the field” or “food service from the processor” for bagged salads. Fresh-cut is increasingly looking like centralized food service and overlapping in food safety issues with centrally processed fresh products (like salsas, fruit salads, or finished salads) that can be used as they are delivered. Listeria monocytogenes tends to be a problem of preparation and storage under cold conditions at processing, as it is for cheese and deli meats as well.

The food safety issues problem of multi-ingredient component products are increasing, as are outbreaks linked to foreign sources of some ingredients. A notable case this year was hepatitis A in Townsend Farms Organic Antioxidant Blend frozen berries, where the source of contamination was attributed to Turkish pomegranate seeds imported by one company (FDA update July 25, 2013).

The process control issues of multi-ingredient fresh food products appear to grow in complexity non-linearly. Intuitively they seem to exponentially increase, where the exponent is related to the number of ingredients. This implies more rigorous testing is needed for each component, before ingredients are mixed together; and I have not seen this discussed in the proposed Rule(s).

In summary, many California processors were increasingly having the food safety problems of conventional cold food processing, and at least some were having fewer problems due to the handling of raw agricultural commodities up until final processing and blending for sale.

Are there more serious problems with other processors, even when their products were sourced from LGMA production (CA or AZ)? Here are three examples:

The CDC has a final update (May 21, 2010) of the O145 (STEC E. coli) outbreak,mentioned in the QAR: "Investigation Update: Multistate Outbreak of Human E. coli O145 Infections Linked to Shredded Romaine Lettuce from a Single Processing Facility". The single processor can be identified as Freshway Foods of Sidney, Ohio, because they issued the linked voluntary recall. The lettuce was from Arizona.

On December 10, 2012, the CDC had a final update on organic spinach and fresh-cut "Multistate Outbreak of Shiga Toxin-producing Escherichia coli O157:H7 Infections Linked to Organic Spinach and Spring Mix Blend (Final Update)". The outbreak was linked to pre-packaged leafy greens produced by State Garden of Chelsea Massachusetts. Bill Marler's comment in a November 12 Marler-Clark announcement "Lettuce Supplier Sued by E. coli Victim" was "Most leafy greens are coming from California this time of year...It will be interesting to see which farm supplied the contaminated product and if that farm has a history of shipping contaminated product." No farm or source of RAC was identified in the last CDC or FDA updates (December 2012).

In January, 2013, the Canadian Food Inspection Agency had a concluding report on an O157:H7 outbreak attributed to shredded lettuce processed at the Sysco Freshcut Produce Toronto (Freshpoint, Toronto). Dan Flynn reported in Food Safety News on January 15, 2013, that CFIA had identified the lettuce as sourced from a CA LGMA member grower.

That seems like a different problem, not of recalls due to State sampling programs but actual outbreaks caused by fresh-cut processor who may not have the same history and experience or layered protections.

The moral hazard comes in if processors fail to understand the limitations of an LGMA type program, take it as a guarantee of safety, and fail to put in sophisticated layers of food safety programs.

From its beginning LGMA was presented as "...A Model Program for Food Safety" (Scott Horsfall FoodSafety Magazine August/September 2008). In the same article it was noted that "...both Canada and Mexico will only allow imports of California leafy green products from companies who are members of the LGMA in good standing." This was when one of the farmers interviewed here, who does not participate in the LGMA, lost his Canadian markets.

Canada also facilitates cross-border access to CA LGMA members.

My position is that if produce is going to enter a fresh-cut market, it needs to be bought only from farms that operate under specialized rules for fresh-cut production -- although the farms can sell to other markets as well. This should be part of the Produce Rule.

Given the variability in performance between regions and individual processors, there also should be specific rules for fresh-cut processing in the Facilities Rule, recognizing that it is in fact, fresh-cut is processing without a kill step and with multiple additional factors that make it inherently more dangerous.

Since growing and processing are tied together for fresh-cut, the basic regulation that fresh-cut processors should have to buy from fresh-cut producers, should be in both Rules. The Produce Rule should have the regulations for fresh-cut growers and the Facilities Rule the specialized regulations for fresh-cut processors.

Furthermore, making everyone unhappy again, the Secretary should determine an exception to the exemptions under FSMA and apply the two interlocking fresh-cut rules to fresh-cut processors buying from any farm, regardless of size.

An example of why this is necessary, and how it might work is Willie Green's Organic Farm, now an 85 acre farm in Western Washington. Their organic fresh-cut salad mixes apparently had spinach as the vehicle contaminated with O157:H7 . Their bagged fresh-cut organic salad mix caused an outbreak and recall in Washington and Oregon. According to Cookson Beecher's article in Food Safety News (July 22, 2013), 13 people were known to become ill and 2 developed HUS. But it was worth it for the owner to work with Whole Foods and develop a HACCP system for his entire farm and processing plant. This allows him access to Whole Foods as a customer.

The two specific fresh-cut rules would free over 90% of farmers in the United States from regulations designed for the largest growers when producing for one of the most hazardous processing markets; unless they themselves choose to participate in these markets, which comes with costs as well as market rewards.

Note added on August 03, 2013:

There has been a large scale cyclospora outbreak this summer.

NBC News reported on August 02, 2013, that the FDA had identified the source of the 2013 Cyclospora outbreak as Taylor Farms de Mexico, one of the Salinas-based Taylor Farms' twelve processing plants. Food service bagged multi-ingredient fresh-cut salads went to chain restaurants. Cyclospora outbreaks in the United States have always been associated with imports, so far. There also is a distinct difference between foreign and domestic food borne pathogen patterns, with outbreaks associated with foreign imports more dominated by human-sourced disease organisms.

Taylor Farms Foodservice released a statement on August 03, 2013, including:

"Taylor Farms de Mexico assesses and tests all water sources, raw product fields; every lot, every day for any risk to our valued customers' products. We are redoubling and enhancing our testing and scrutiny in these areas to further assure food safety….

"Taylor Farms de Mexico, S. De R.L. de C.V. exclusively provides fresh cut and value added produce to the foodservice industry. The company's operations include a state of the art processing plant, industry leading SmartWash food wash enhancement system for mitigation of cross contamination, and progressive field testing programs." [Italics in original statement].

The outbreak investigation, and environmental investigation reports may indicate the root source. SmartWash, in part, appears to stabilize effective chlorine use despite high

organic matter loads in wash solutions [J Food Sci. 2011 Apr;76(3):M218-24. doi: 10.1111/j. 1750-3841.2011.02046.x. Epub
2011 Mar 14.]

The CDC's general warning on cyclospora, however, includes:

"On the basis of the currently available information, avoiding food or water that may have been contaminated with feces is the best way to prevent cyclosporiasis. Treatment with chlorine or iodine is unlikely to kill Cyclospora oocysts. No vaccine for cyclosporiasis is available."

http://www.cdc.gov/parasites/cyclosporiasis/prevent.html

To me this indicates a continuing problem that has to be addressed in foreign sourced produce, in this particular case for fresh-cut food-service processing. My impression is that the learning curve on cyclospora is behind O157:H7 and salmonella for all U.S. based processors.

The California LGMA pathogen metrics were designed using generic E. coli as an indicator of contamination; I did not find further specific metrics that would have covered Cyclospora, and, as mentioned in other sections, it is hard to find the correlation between generic E. coli and Cyclospora. It is a gap in the GAP metrics.

The moral hazard argument still seems to hold for the pathogens that they have tried to mainly control for in California: mainly pathogenic Salmonella and E. coli O157:H7

SECTION VIII: SCALE AND HAZARD

Most of this Comment is scale neutral. There are major groups just working on the impact of the proposed Rule on smaller commercial farmers, local family farms and how the relative impact of the proposed regulations will differentially effect farms by size or the ability to absorb new costs. There will be similar concerns about processing size and the proposed Facilities Rule under FSMA.

I have only a few different points to make about this.

The statistical distribution of farm size in the United States, and in produce production in the United States, is more highly skewed than either wealth or income. Normal statistics based on a normal ("bell-curve") distribution are fairly meaningless.Relatively few farms produce over 80% of many produce crops. A few thousand farms produced over 80% of fresh produce. They have differentially significant impact on national produce safety.

I studied this in 2008 using 2002 USDA data and the then more recent CA and AZ data for lettuce, as a leafy green which did not go into processing with a kill step. Other crops, such as almonds, have higher concentration of production.

My suggestion is that these largest farms should receive special attention, because they have national impact, the types of regulation in the proposed Rule were actually designed for their scale of production, the costs of regulation can be more easily, absorbed, and many of them are already under CA LGMA and similar rules so many costs (not all) have already been accounted for.

I would not regulate by farm size, however, because of the history of acreage limitation on receiving federal water from the West Side Canal in California. Don Villerejo from the California Institute of Rural Studies (CIRS) is cited in two references on farmworker health in the rule. But he and CIRS, and others,did major studies on how large farms continuously evaded federal acreage limits, no matter how many times those limits were raised. I would expect the same to happen if one had special rules for the largest farms because of their size, even though the proposed rules seem to fit them the best.

Most of the largest farms also are producers for the fresh-cut market, however, and special regulation of producing for an inherently more dangerous processing use would include them. This also is scale neutral, as it should be, since even the smallest producer growing for fresh-cut should have to meet stricter rules.

Regulating farm production for fresh-cut processing, as well as categorical processing rules for fresh-cut in the Facilities Rule -- where this is currently absent -- would also cover most of the largest produce farms with the greatest national impact.

Dave Runsten points out in his interview that there may be areas where smaller farms can have greater food safety than larger farms, and I support his view that more research needs to be done on this possibility.

The only other comment on scale I have is on employment. The well-established organic specialty and truck farms I work with provide permanent jobs at a rate of from one job per acre to one job per ten acres. The field crops growers I work with provide less than one job per 600 acres. Regulating poorly for produce safety will not only negatively impact farms inversely to farm size. It will have an even greater negative impact on employment and rural economic health, particularly as people decide whether or not to even enter farming.

IX. ONLY AN IDIOT WOULD NOT BE CONCERNED WITH FOOD SAFETY.

This is a quote from Tom WIlley, a successful long time organic farmer on 75 acres who probably will be fully covered by the proposed Rule. New regulations will have less impact on his farm, because he already takes many of the safety steps, on the one hand, and many of the the documentation steps because of organic rules and the organic law. They already do pathogen testing. He uses drip irrigation from a pathogen

tested well and uses a different pathogen tested well for wash water. Organic compost is already tested for O157:H7 and salmonella as well as indicator organisms. They already have a comprehensive employee food safety program. They already have their own farm-specific GAPS plan.

They stopped producing salad mixes years ago because of the inherent food safety risks, and do not bag any produce for the same reason. He is very research and science oriented and takes food safety extremely seriously.

He can't see the reason for a 45 day rule for applied compost, when that compost has been effectively tested for the absence of human pathogens.

Tom Willey opposes most of the approach of the proposed Rule; he has a different view of the role of complex micro-organisms and biological diversity as essential to, and not opposed to, food safety. Surprisingly, most of his views are almost the same as Will Daniels, the organic processor who generally supports the proposed produce Rule. In the Earthbound Farm interview Daniels said they differ with the proposed Rule primarily in seeing balanced healthy ecosystems as promoting food safety and not impeding food safety.

Like Tom Willey, Will Daniels opposes a sterile approach to agriculture. Both of them see a sterile approach as creating a vacuum which human pathogens can fill. Daniels also made some points I do not remember hearing even from Jo Ann Baumgarten of Wild Farm Alliance:

What really happens when you eliminate habitat surrounding farms is you invite animals into the production fields.

and

What really happens when you consider fish, ducks and plants to be hazards in an irrigation pond and turn it into a lined, sterile-looking container is that you create a petri dish for human pathogen increase.

Will Daniels has a very different view than most of the processing industry and large buyers: that there is a positive role for farm habitat and that biological complexity is promoting food safety, not endangering it.

Tom 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. He is the person who drew my attention to WF Brinton's work on sampling commercial greenwaste and animal manure based composts on the West Coast for human pathogens (O157:H7 and salmonella) as well as indicator species -- and the many problems that were found. His critical, science based approach should fit with WIll Daniel's program of validating and documenting safe production of composts.

Tom Willey cannot understand why neither the produce industry nor the proposed Rule takes on animal CAFO's as a constant source of increasingly dangerous, robust, antibiotic resistant human pathogens that flood into the farm environment. He also came up with the notion that as genomic testing advances one could sue the source of a specific pathogen strain coming from, for example, a CAFO. This is a free market approach that could become a legal doctrine on pathogen drift, similar to pesticide drift.

Will Daniels is supporting research on feed ingredients that might eliminate O157:H7 and other STEC E. coli in cattle.

Earthbound was the first company to put statistically valid test and hold both before entry of produce into a processing plant and before finished product is released. Both farmer and processor take food safety seriously. But they have a very different orientation than either the CA LGMA or the proposed Rule. Sometimes this means they are stricter, for example when advocating for human pathogen testing of key inputs on-farm.

All of the persons I interviewed, including some not reported here, support additional research because they are well aware of the enormous gaps in knowledge that exist. The proposed Rule does not seem to respect how much is unknown and, frankly, neither do some of the consumer groups advocating for regulation without, sometimes, appearing to value effectiveness of regulation.

There is increasing evidence that some kinds of microbial diversity in soil, water and on plant root or above ground surfaces are beneficial to food safety, and their destruction decreases food safety. This is a key part to an alternative approach to the Rule.

X. EVOLUTION OF PATHOGENS CONTINUES

Rhizosphere (root affected zones of soil) and phylosphere (above ground plant surface colonization) have received extensive research attention over the last ten years both for human pathogen interaction and for the microbial ecology of human pathogens in the environment. Internalization of human pathogens within plants is studied with entry points through roots, through flowers, and into leaf or seed coat tissue penetrating enough, or protected enough by surface structures, to make washing ineffective.

Frederick Ausubel at Harvard and Massachusetts General Hospital (MGH) studies the genomic interactions of an opportunistic non-fastidious human pathogen Pseudomonas aeroginosa which can also infect the model plant Arabidposis species (small crucifers; broccoli and kale relatives). It's depressing how good a plant pathogen this burn-patient derived strain is. It also can infect the worms used as models for animal research (C. elegans) and model insects (Drosophila) as well as the humans it was isolated from.

"Remarkably, many bacterial and fungal pathogenesis-related genes that are required for mammalian pathogenesis are also required for pathogenesis in model non-

vertebrate hosts." (Ausubel, research interests, Harvard website). Plant defenses and human defenses against human pathogens are related systems.

What we have seen as "emerging infectious diseases" since O157:H7 showed up on apples and in apple juice are increasingly opportunistic human pathogens that remind one more and more of P. aeroginosa. It was very unexpected that human pathogens could survive on plants, or that thousands of years of successful control, such as counting on acidity of foods or drinks, would fail, for example in apple juice or cider.

We really really need to stop providing conditions that select for increasingly opportunistic, virulent, antibiotic resistant and uncontrollable new strains of human pathogens in the human, animal and plant environment.

A "sterile" approach to produce safety, like calling for chemical treatment of irrigation water in the proposed Rule, on hundreds of thousands of acres in region after region, is both ineffective and counter-productive. Besides destroying the microbial ecosystem that could have provided some competition with, predation on, and control of human pathogens, it simply acts as a massive selection system for even worse human pathogens.

The foundation of long term produce safety should be to prevent further emergence and evolution of even worse human pathogens on-farm, in the farm environment and on produce. This is not even discussed in the proposed Rule.

XI. BENEFICIAL MICROBIAL DIVERSITY AND PRODUCE SAFETY

Let me just give the briefest of sketches of some research that supports this.

In "**General Suppression of Escherichia coli O157:H7 in Sand-Based Dairy Livestock Bedding**" Westphal et al. looked at "...if sand-based bedding also supported the microbiologically based suppression of an introduced bacterial pathogen" using O157:H7 as the introduced pathogen. They found that sand worked faster for supporting microbial suppression, 3 log reduction in one day, all bedding materials tested supported a 5 log reduction over time.

Genomic analysis of suppressive micro-organisms identified diverse bacteria from five different phylum, "...only a few of which have previously been identified in livestock manure. Such data indicate that microbial suppression may be harnessed to develop new options for mitigating the risk and dispersal of zoonotic bacterial pathogens on dairy farms."
(APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Mar. 2011, p. 2113–2121)

In "**The Microcosm Mediates the Persistence of Shiga Toxin-Producing Escherichia coli in Freshwater Ecosystems**" Mauro et al. found

"...that depletion of microbes in the water leads to a considerable increase in the persistence of STEC, an effect that can be mitigated by adding grazing protists to the water"

and that

"Our results demonstrate that the microcosm can dramatically influence the persistence of STEC in aquatic ecosystems and that the overall impact by microbes on STEC strains is fundamentally different from that of non-STEC strains of bacteria."

They stress how complex and context dependent such effects are.
(Applied and Environmental Microbiology, August 2013 ,Volume 79 Number 16 p. 4821–4828)

In "**Quantification of Persistence of Escherichia coli O157:H7 in Contrasting Soils**" Ibekwe et al. found for methyl bromide and methyl iodide on sandy and clay soils that if soil is contaminated with E. coli O157:H7,

"fumigation alone may not eliminate the pathogen, but may cause decrease in microbial diversity which may enhance the survival of the pathogen."
(Applied and Environmental Microbiology, August 2013 Volume 79 Number 16, p. 4821–4828)

In "**Colonization and Internalization of Salmonella enterica in Tomato Plants**" Zheng et al found that different Salmonella serovars can find niches in fresh tomato rhizospheres and phylospheres, in experiments using soil from Virginia's eastern shore. They also found greater invasion immediately after transplanting (which brings transplant production conditions into the food safety equation). In their discussion they note:

"interior root colonization might occur passively through wounds in roots that are damaged during transplantation. Moreover, methyl bromide has had a long history of use in tomato cultivation as a soil fumigant in the eastern United States, and recent metagenomic studies have shown that such practices have diminished overall soil microbial diversity, perhaps increasing the potential for Salmonella colonization and persistence in the soil."
(Applied and Environmental Microbiology, April 2013, Volume 79 Number 8, p. 2494–2502)

In "**Lettuce Cultivar Mediates Both Phyllosphere and Rhizosphere Activity of Escherichia coli O157:H7**" Quilliam et al. found cultivar-specific effects on colonization by E. coli O157 looking at 12 lettuce varieties. (SImilar genetic differences were found by Ausubel in the model Pseudomanas-Arabidosis systems):

"However, the influence of cultivar in the rhizosphere was the opposite to that in the phyllosphere, and the higher number and activity of E. coli O157 cells in the rhizosphere may be a consequence of them not being able to gain entry to the plant as effectively."

"In this study, we have demonstrated that the potential for E. coli O157 colonisation

of lettuce is cultivar dependent. Metabolic activity of E. coli O157 that have become internalized or very firmly attached to the leaf was much greater than those cells on the leaf surface, which suggests that these cells are not only persisting in this environment but are actively metabolizing plant-derived nutrients."
(PLoS ONE | www.plosone.org March 2012 | Volume 7 | Issue 3 | e33842)

Prevention of leaf (phylosphere) colonization by human pathogens would appear to be of great importance in leafy green production. Phylosphere microbial ecological studies are extremely complex.

In a comprehensive mini-review, "**Survival of Escherichia coli in the environment: fundamental and public health aspects**" van Elsas et al. note:

"The availability of resources such as carbon substrates probably is the main critical factor that affects the persistence of E. coli in open environments such as soil and water."

Which has serious implications for the form and extent of fertilization in produce production, (discussed in the next article).

"Contrary to the declining populations that are often seen in natural habitats, populations of E. coli can increase in such substrates under sterile conditions, that is, without predatory, antagonistic or competing organisms. This indicates that the natural microbiota in such cases has an overriding effect on survival."
(The ISME Journal (2011) 5, 173–183)

In "**The rhizosphere microbiome and plant health"** RL Benrendson et al. describe the general control effects plants exert over the root zone microbials. 40% of photosynthate can be directed to the root zone, which provides a nutrient rich environment that contrasts with surrounding soil.

Finally, representing an enormous body of work in the Netherlands by Ariena H.C. van Bruggen and colleagues is "**Ecology of E. coli O157:H7 and Salmonella enterica in the Primary Vegetable Production Chain**". Franz and van Bruggen, among many other findings, discuss how the over-abundance of primary nutrients favors human pathogens by suppressing microbial and soil ecological diversity. DOC (dissolved organic carbon) was a key factor in O157:H7 survival comparing 18 pairs of organic and conventionally farmed soils. Tom Willey, in his interview, compared this effect to the biodiversity dead zones in the gulf of Mexico at the mouth of the Mississippi river.

This gives some hope that fertility and soil structure management, easier to conceive than direct beneficial microbial management, could both prevent nutrient run-off into streams and rivers and indirectly improve conditions for overall produce safety.

XII. A GOAL OF INTEGRATED PATHOGEN MANAGEMENT

How does one work effectively to control human pathogens in co-operation with beneficial effects of other micro-organisms in the soil and other ecosystems?

One model for how to integrate beneficial micro-organisms, and other aspects of complex ecological diversity, with produce safety is integrated pest management (IPM). IPM was developed primarily for control of insect pests and plant pathogens in crop management. When done right, it allows a maximum effective use of crop protectant chemicals at a minimal cost, by knowing when an economic thresh-hold can be predicted from climate reports and crop stage, limiting pesticide use to effectively timed applications, and preserving beneficial insects or other natural control organisms. There is even a remnant of IPM integrated into GMO production of cotton and other field crops, when *refugia* are set aside to delay or prevent the election and evolution of insects resistant to pesticides.

One way of looking at IPM is that it was developed as a compromise between chemical over-use and relying only on bio-control. If one gets in a chemical arms race with insects, using every pesticide available, the insects usually win in the end. They develop resistance, and natural control by beneficial insects through predation and parasitism has been destroyed. Problems get worse.

The same issues can be seen for herbicides, as the wide-spread emergence of glyphosate tolerant weeds, even super-weeds, has followed the introduction of glyphosate tolerant crops and the over-reliance on one chemistry, very widely applied, for control.

It is exponentially harder to win an arms race against micro-organisms, with their short generation times (20 minutes for laboratory E. coli strains) and their ability to laterally transfer key pathogenic and resistant traits between species (horizontal transfer). They also evolve their mechanisms of evolution; where resistance to one class of antibacterials seems to pre-adopt strains to more rapid development of, for example, antibiotics.

An integrated pathogen management program for produce should be an overall goal that is not in conflict with federal regulations for farming.

Beyond that, there is the notion of an integrated healthy ecosystem for plants, animals and people. They all affect each other. It may be the only achievable long-term pathway to produce safety. Support for this has surprised me while working on this Comment.

XIII. A ONE PARAGRAPH ALTERNATIVE PRODUCE SAFETY RULE

Here is Will Daniel's three sentence version of a produce safety rule:

"Perform a risk assessment of your product in your system; understanding their use at the consumer level (washed, eaten raw, in a bag, open, etc.). Create a plan that mitigates those risks and validate them. Verify control through documentation."

That seemed a little terse so I rewrote the various versions I heard from him as follows:

(1) Every operator and farmer has to do a specific risk assessment of how their operation will affect food safety to the consumer.

(2) They have to design a control plan to mitigate these risks and validate that their plan works.

(3) They have to follow the plan and verify that they are following the plan by documenting it.

(4) Other aspects of the Rule should only be given in Guidances.

The fourth sentence is a general position taken by many of the larger produce industry groups, including the LGMA, as well as Earthbound Farm.

Will Daniels prefers the version in quotation marks. This version could also replace the entire proposed Facility Rule.

XIV. MORE SAFETY WITH MINIMAL REGULATION

My view is that great statistical improvement in produce safety, with the least impact on most farmers, could also be covered in a few -- different -- rules. The FDA can best regulate persistent hazards, not intermittent or random hazards.

(1) All produce farms should follow the rules for use of manure and compost in the Organic Farming Act. This also means sewage sludge and solids are banned from produce production.

(2) No harvesting of produce contaminated by feces (or possibly contaminated).

(3) The FDA has a much better ability to regulate and control the suppliers of inputs and services before they enter the production chain on farm. These include many groups that have not traditionally seen themselves as part of the food safety chain: fertilizer and compost makers, pesticide applicators, irrigation districts, public health officials involved in human waste disposal, and others. There should be more effective

and critical regulation at the points of control ***before*** inputs are allowed to be used on farm.

(4) Farm inputs including water, composts including greenwaste, etc. should be tested for human pathogens.

(5) Manure or greenwaste or other inputs contaminated with human pathogens cannot go directly into inputs (like composts) sold to farms. They require a primary processing step to eliminate human pathogens first. Otherwise they can stay with the CAFO's or the urban sources respectively (allowing free-market responses).

(6) Fresh-cut requires specific regulation from farm to fork.

Registration of farms that produce for the fresh-cut and prepared-fresh market. Specific rules for production apply to farming for these high-risk end uses -- they might look like a modified version of the proposed Rule.

Processors buying produce for fresh-cut or prepared-fresh use must buy from registered farms and document it. Registered farms can sell to any market, however.

Fresh-cut and prepared-fresh processing without a kill step should follow procedures developed for high-risk processing, without a kill step; as is the case for sprout production.

(7) Seeds for sprouts should be produced for sprout use under a rational Guidance. Only seeds grown under the Guidance should be used by sprout producers.

(8) FDA should focus on food processing enforcement and regulation, its traditional skill-set. On farm the FDA should focus on washing and cleaning operations, and equipment, where the hazards are most like those of processors.

(9) Farms should adjust production practices and use product-testing before sales to compensate for identified hazards. Contamination equivalent to flooding should probably follow the same procedures (crops can be lost entirely).

(10) Special hazard-combination rules. Separate out the persistent problems of a particular crop in a particular region for special rules and guidances until the problem combination is solved.

There are some non-regulatory steps that could complement this. "Smart water systems" reporting could provide information to farmers. Declaring salmonella an adulterant of poultry failed in the courts. Declaring antibiotic resistant salmonella both an adulterant and a public health hazard might succeed. A ten year program of eliminating STEC E. coli in cattle and dairy could be a cooperative project.

If the FDA becomes the best source of current pathogen and pathogen control information for farmers, they could build a non-enforcement relationship with them. I would encourage this kind of approach.

I may be the only person who includes this as a major hazard category but I see new equipment and rapid growth as specific farm and processing hazards, based on the outbreak record. I do not see them discussed as topics for for produce safety but I have seen them discussed for restaurants.

There is a kind of compensatory hazard with brand new equipment that is supposed to be the safest available. Its not obvious that, like a new battleship, it needs a shakedown cruise before one knows it will work. Used equipment, new to an operator, is supposed to have worked previously.

They often are accompanied by a separate hazard, increased operational throughput, sometimes to pay for the new equipment. Safety gets trampled

This holds from the first New England apple juice O157:H7 cases through Odwalla, the spinach outbreak, and Jensen Farms listeria on cantaloupe.

I would encourage the FDA to identify new equipment and economic pressure as risks to growers, handlers and processors and develop specific expertise in prevention that would be available to those who request assistance.

I also was asked to include a mention of mixed farming. For now, all I can say is there needs to be a high bar. If mixed-farmers can maintain a human pathogen free herd or flock, then there should be more options open to them.

XV. CONCLUSION

For good and substantial reasons, discussed above, the proposed Rule should be rejected.

The QAR, the Analysis of Economic Impact and the prologue to the Rule contain hundreds of specific questions, asking for comment. They almost read like a plea for for help. Perhaps the FDA staff who wrote the proposed Rule were restricted by political decisions that were made before they began writing. I do not know the constraints they were working under. I hope some of the questions have been answered in this comment and will be helpful.

This Comment is supposed to give the twenty-thousand foot over-view. I tried to give enough detail to illustrate the main points. The proposed Rule does not look good from 20,000 feet. It looks even worse up close.

I could write a much more detailed critique, and may later, but I have confidence most of the technical points I have will also be made in the scientific peer reviews. In a way I

feel like the vet who had been asked to do a root canal on a chicken. It's an inappropriate procedure and wouldn't do much for the chicken either.

It might have been a better process if the peer reviews of the QAR and the Analysis of Economic Impacts had been done first, the supporting documents and the proposed Rule had been revised in response, and then revised documents and a revised Rule had been put out for public comment.

If you were to base the Rule on the actual text of the law (FSMA) and the actual evidence on the record you would leave all farming operations, from planting to harvest, alone. The FDA would start with processors of fresh produce, move on to handlers and then to handling operations that occur on-farm -- whoever does it. Using contaminated wash water is a known disaster waiting to happen, for example

There are known hazards on-farm. Some of them occur at random; well then, food safety could be greatly improved without trying to cover every case, including the random and the speculative (the possibility of a pathogen being present requires regulation without evaluating its significance). But systemic hazards seem worth covering, and so do repeated outbreaks from the same crop-regional combinations.

But doing nothing about farming operations through harvest would be better than the proposed Rule, meaning that it would do less harm. The Rule in its current form does a lot of harm; to farmers.

It helps processors. It puts the burden of processing safety back onto farms. It's true, if all produce came to processors absolutely pathogen free all they would have to worry about are the problems of processing safely. Like Peanut Corporation of America and salmonella? That's unfair to other processors. But there are enough places to contaminate produce after harvest for the FDA to be concerned about.

It might have been better to state reasonable objectives and let farmers and others find their own means to achieve them. There is a kind of perverse offer of flexibility in the proposal: if one can show rigorous scientific evidence of an alternative, an amorphous bureaucratic process *may* allow this to replace the non-validated and often unscientific procedures detailed in the Rule.

Zero-risk is not even a rational goal for produce safety. Nothing in the proposed Rules or in this comment even address solving the problems of VBNC (viable but non culturable) human pathogens in the farm environment, or asymptomatic human carriers of disease, for example.*

A long time ago, someone much more intelligent than I am observed that this kind of rule:

"Resembles some self-willed and ignorant person, who allows no one to do anything contrary to what he orders, nor to ask any questions about it, not even if, after all,

something new turns out for someone which is better, contrary to the prescription which he himself has laid down." **

I think he's got the FDA's number.

One never knows what small cultural factor will be the last straw.

I can make a guess for this Rule, though. When farmers all across the country find out they cannot bring their own dog with them on their own farm, I think any co-operation will be over before it begins.

The Secretary would be a fool to sign it.

Dan Cohen
Maccabee Seed Company
Davis, CA

August 01, 2013

**Cooper and Hutchinson (editors), Hackett Publishing Company, 1997: Plato, Complete Works. Statesmen, page 338.

* If you prefer Aristotle consider the following:

A syllogism for produce safety and environmental destruction

Frogs and other amphibians carry salmonella.

Wetlands and ponds are habitats for frogs and other amphibians.

Removing wetlands and ponds will help prevent salmonella from contaminating produce.

[More abstractly: m is a possible source of human pathogens, n is a habitat for m, removing n protects against human pathogens. Apply to all n given m. That's the logic of sterilization of the natural world to increase produce safety.]

Comments from Dr. David Acheson, emails July 2013 with Daniel B. Cohen, Maccabee Seed Company; for attribution.

David Acheson was Chief Medical Officer and then Acting Director at FDA's CFSAN (Center for Food Safety and Applied Nutrition). which was followed by being named, first, Assistant Commissioner and then Associate Commissioner for Foods. Before joining the FDA he was Chief Medical Officer at USDA's FSIS. He left FDA in early 2009 and joined Leavitt Partners, LLC in Utah, where he oversees their Food and Import Safety Practice.

The produce rules are certainly causing some serious consternation amongst some sectors of the produce industry. My read is that is a mixed bag. The leafy green folks are already doing a lot of this so that is not a big lift. Others are clearly not, like tree fruit and they are worried about the impact when they see their products as very low risk

We also have this new "mixed type facility" that is really hard to figure out as to who is in that and who is not in that and then what exactly they need to do.

Considering it is supposed to be science and risk based there are few flaws in the logic and a need for work to figure out all these issues. While I understand how FDA cannot write rules for each type of produce, writing a one size fits all rule is almost impossible. I also think that there are sectors of the produce industry where FDA has some serious knowledge gaps that need to filled which I know they are working hard to fill. So the more produce industry sectors offer help to FDA the better at this point.

We can only hope that the comments help sort it out. We are going to put in some comments on behalf of clients but don't plan extensive comments at the moment

History has taught us the criticality of risk based thinking for preventive controls applied to produce. Essentially translating Good Agricultural Practices from a guidance to a regulation is a great way to approach this. However, the way the proposed rule has come out has raised a number of complications. I worry that so many are excluded, and while understanding the logic of protecting small business, a much better approach is to require all to follow basic standards and for the government to provide the necessary training and education through extension

services – but unfortunately that is another program that is being decimated through lack of funding.

Additional information (Dan Cohen)

In 2007, as Assistant Commissioner for Food Protection, Dr. Acheson wrote an FDA letter of support for an initiative I was working on to create a new kind of Medical Cooperative Extension service at the Land Grant Colleges. This may still be relevant to food safety and the broader aspects of the proposed Rule.

Extension specialists in Medical Extension would have as their area the fate of human pathogens in the environment, including urban, medical and agricultural. These systems all interact. At least in our experience, Cooperative Extension has been a problem solving organization with excellent research skills. They are not inspectors or investigators or enforcers. Farmers, businesses, and people in general, can work with them.

Extension at the Land Grants has traditionally been part of USDA funding. Medical Extension would have a broader base with resources brought in from HHS (Health and Human Services, DHS (Department of Homeland Security) and others. Medical, veterinary, clinical and epidemiological researchers could learn a lot from the culture of Cooperative Extension when it is at its best.

We made considerable progress at UC Davis, with the then Chancellor, the then Dean of Agriculture and the (still) director of the Western Institute for Food Safety and Security (WIFSS), Rob Atwill. But Chancellors changed, administrations changed, the economy collapsed and Cooperative Extension continued to be decimated.

Some new Extension Specialist positions at UC Davis do come close to this role.

We also discussed the role of better funding for research to mitigate the more serious and lethal consequences of infection by food-borne human pathogens, such as hemolytic-uremic syndrome (HUS) as a consequence of infection by E. coli O157:H7 and related pathogens.

Both initiatives still seem relevant, seven years after the spinach O157:H7 outbreak.

Scott Horsfall, Executive Director California Leafy Green Handlers Marketing Agreement (CA LGMA) Interview July 16, 2013 (Daniel B. Cohen, Maccabee Seed Company, Davis CA, edited. For attribution

The LGMA is supportive of FSMA, in general, and pleased that the proposed rules align well with what they are already doing. The produce rule identifies the key risk areas for food safety. Staff and leadership from the FDA did visit with the LGMA and discuss how it works, including staff who were writing the rules.

The LGMA, however, is much stricter than the proposed rule in its details and content for growers. The FSMA rules are not simply a copy of the LGMA.

On the other hand, the LGMA has concerns that the 7 day testing requirement in the FSMA section on water is excessive. Also, while the LGMA is designed to have flexibility to change its technical standards as new information is developed, the FSMA proposed rule does not have flexibility built in. For this reason they are supporting a wider industry position that the metrics in the FSMA should be FDA Guidances and not set inflexibly as Rules.

The generic E. coli standard for water is not perfect, but neither are any of the general indicators of contamination. It may be the least bad indicator and some standard needs to be used.

Both farmers and processors in California have been working for seven years now to improve their respective safety practices. The LGMA was designed for lettuce and leafy greens produced in California and it seems to be working here as part of a coordinated effort. They did not ask that these rules and metrics be applied on a national scale or to other crops with different safety issues and do not claim to know what would work for other regions and crops.

There have not been, as of now, any studies documenting an improvement in the safety record after passing the LGMA as compared to before, but there have not been the same kind of severity of outbreaks. The impression is that the safety results have improved. It would be difficult to separate out processor improvements, from farm metrics under the LGMA and from the effect of private contracts that include further steps required by different buyers.

As far as Scott knows, use of private data on rejected lots or recalled lots has not lead to identifying problem areas on farms that one could learn from; only the more complete state and federal investigations done following outbreaks have had some limited success.

The most promising changes in produce safety he sees coming out of research are: developing a more complete picture of risk and risk mitigation. The LGMA has supported the Center for Produce Safety (CPS) research program at UC Davis. Scott thinks that the research has validated what were best estimates on some of the metrics,

like distances and buffers from contamination sources. One of the more interesting results of research is the great importance of what happens on-farm close to harvest: even the last day or the last few hours before harvest.

Ideally research like this could lead to easing some of the burdens on produce farmers as more critical areas are identified.

Although the LGMA itself is not involved, several large growers from the Salinas area have an initiative to work with the Cattlemen's Association to try and reduce pathogens at one of the sources; for example by testing different commercial immunizations against human pathogens carried by cattle.

My overall impression is that Scott sees the LGMA as a necessary layer in a series of layers of protection from farm to fork, that will improve over time. Some of the metrics started as educated initial hypotheses. Over time they may be validated and confirmed, replaced with better standards, or in some cases reduced as un-necessary. They work for the California leafy green produce industry.

The spring-mix category under LGMA includes many different produce types, and can be open ended. Inclusion depends on what various processors put in their fresh-cut mixes. In the end what it means is that handlers under the LGMA have to purchase any ingredient from a farm producing according to LGMA rule.

Interview with Tom Willey, T&D Willey Farm, Sunday July 14, 2013. Daniel B. Cohen, Maccabee Seed Company.

Tom Willey is co-owner with his wife Denesse of a 75 acre certified organic truck farm near Madera in California's San Joaquin Valley. The motto above the logo on their home webpage is attributed to Sir Francis Bacon who inspired England's scientific revolution.

"Natura enim non imperatur, nisi parendo" translated as: "Nature cannot be ordered about, except by obeying her."

They have been farming since 1980 and been certified organic by CCOF/NOP since 1987. Tom also used to work in conventional processing tomato production. After leasing land to farm organically for many years, they were forced to move and purchased their own farmland; changing land being a particularly tough thing to do in organic production. The year-round, they have about 60 full-time workers employed.

They grow for local markets, and ship regionally and to some extent nationally. They formerly shipped to Canada until the Canadian government adopted an import rule that any leafy greens from California had to come from a CA LGMA handler. They are not associated with the CA LGMA.

Tom is the source of my quote: "Only an idiot would not be concerned with food safety."

The impact on their farm of the FSMA rules would be less than one might expect, even though they are fully covered by the rule.

* They already have a comprehensive employee food safety program.

* They already do pathogen testing.

* They source irrigation water separately from wash water and drinking water from two wells on the property.

* Both water sources are regularly tested for fecal coliforms, which also acts as a warning signal against new or emerging problems, such as loss of well integrity.

* The whole farm is on buried or surface drip irrigation from one well, so they are in the safest categories under the proposed rule.

There is no contour gradient from the nearest animal facility towards their farm, which might provide a pathway for leaching towards their wells.

* They purchase OMRI certified dairy compost from a long-time highly respected supplier who tests, documents and certifies absence of detectable O157:H7 or salmonella, along with other tests.

* Paperwork and record-keeping goes along with NOP organic certification and other buyers' requirements so it is not a new burden.

* They stopped producing salad mixes years ago because of the inherent food safety risks.

* They do not bag any produce because of the inherent food safety risks.

* They have their own farm-specific GAPS [formally defined good agricultural practices specified for their operation, crops, growing conditions and specific hazards].

The impact on his own farm may be minimal but Tom was relentless in his criticism of the proposed rule. Many of his points were also made in his testimony against a proposed Federal Leafy Green Marketing Order. A written copy of his remarks from one of the USDA hearings is reproduced in full below. Direct quotes in what follows are from that document. They apply equally to the FDA's FSMA proposed rule.

He sees the overall approach as dismissive of and destructive to the development of food safety enhanced by biologically complex ecology on farms, particularly of soil micro-organisms.

He opposes a sterility approach to food safety on farms and heartily endorsed my sprout analogy. This goes: if a sterility approach to entire farm ecosystems worked, treating entire farms like food facilities, then the FDA should have been most successful in regulating the one arena in which fresh produce production most resembles food processing in an enclosed facility: that being sprout production. There appears to be little ecology or complex biological ecosystem in indoor sprout production. The only inputs are seeds and water. And... the human pathogens that can be brought in by seeds.

After over 15 years of layering more specialized guidelines and regulations on sprout production by the FDA, a continuous record of sprout-associated outbreaks persists.

Tom's view of the problems in sprout production derives from his understanding of plant-microbe interactions in soil ecology. Plants deliberately feed nutrients and other materials into the soil through their roots to shape favorable rhizosphere ecology. Sprouting seeds do the same thing, but there is no soil rhizosphere ecology to interact with in closed container [drum] production of sprouts without soil. In the absence of appropriate soil micro-organisms human pathogens may benefit from these nutrients to survive or thrive under the favorable sprouting environment. Gnotobiology [organisms produced in sterility without their associated microbial ecology] creates a dangerous vacuum. Human pathogens, if present, can fill that vacuum.

There are similar issues in the processing of fresh-cut bagged mixes. Leakage from cut produce is a nutrient broth that both human pathogens and other micro-organisms can take advantage of, in a moist enclosed environment. This can be a very risky stage, especially when shipped across country in special incubator-like bags which van Bruggen says are deliberately designed to create low oxygen environments, favoring facultative anaerobic pathogens.

His view of compost production and its role on farms is similar. Heating uniformly to a sufficient temperature through one phase of microbial activity is only part of the pathogen-control process. Thermophiles do not eliminate pathogens entirely. A time-consuming curing process during cool-down is critical for a proliferation of beneficial microbes.

“The cornerstone of my farm’s fertility program is thermophilically digested composts from both dairy cows and urban green materials. These are produced to rigorous NOP standards and regularly tested for the absence of human pathogens. Robust and diverse soil microbial communities, enhanced by additions of quality composts, have been demonstrated to be less hospitable environments for human pathogens by excluding or more quickly eliminating them. There is no recognition given this proven strategy in LGMA metrics, on the contrary a great pall is cast over the use of manure or compost that would frighten your average grower to death....” [Similar metrics characterize the FDA’s proposed Rule].

However, despite there being many lots of compost made locally under varying degrees of thoroughness, there are not many reports of people getting sick from compost associated pathogens. It cries out for more research.

Willey sees the FDA ‘s produce safety rules as suffering in part from omissions:

* In the proposed Produce Rule, CAFO’s and their continuing interjection of increasingly dangerous human pathogens into the farm environment don’t even receive a mention.

“The antibiotic resistant and increasingly virulent organisms contaminating our produce from time to time are mutant creatures introduced into the larger environment from confined industrial animal operations across the American countryside. CAFO’s using as much as 70% of the nation’s annual antibiotic supply in subtherapeutic feeding regimes to mitigate crowding, stress and unnatural diets have been documented by the Pew Commission on Industrial Farm Animal Production to have created at least several of the very dangerous pathogens which episodically threaten today’s produce supply...

“Why our vegetable industry refuses to throw rocks at the glass house of industrial animal production is beyond me to comprehend. Instead we pretend it is possible to superimpose a paradigm of sterility over vegetable farms by implementing the more extreme practices suggested by LGMA or rogue buyers and processors...”

Tom then made an interesting observation on technological development and the law. We can now continue tracing outbreak strains with high specificity much farther back along the chain of contamination, possibly to individual CAFOs, or even animals. It may be that torts and liability will do what regulators have failed to do.

[If actual economic costs were recovered for animals vectoring human pathogens; washing of meat, in the case of STEC on beef, not even bothering in the case of salmonella on poultry; and leaving feces to contaminate the rest of the environment, including produce farms, then over time the animal industry would necessarily adjust. In our conversations I suggested the terms “genomic trespass” and “pathogen drift”. The latter term with its analogy to “pesticide drift” which is an already well-recognized area in the law for damages, may be better --- dbc].

* The proposed rule fails to deal with fresh-cut produce as a unique major contributor to outbreaks and recalls with unique hazards.

He also opposes the 45 day rule for applied compost when that compost has been effectively tested for absence of human pathogens.

Tom Willey is one of the most scientifically literate people I know on the subject of soil and plant microbial ecosystems and interactions. He suggested new references to me from a Wageningen University, the Netherlands, group that includes Ariena H.C. van Bruggen’s work; W.F. Brinton’s Woods Hole Institute work on testing for both fecal indicators and pathogens in commercial composts in Washington, Oregon and California (which makes for queasy reading); and the work of R.L. Berensen’s group at Utrecht University on the relationship between the rhizosphere microbiome (microbial ecology of the root-influenced zone of the soil) and plant health.

He recognizes that extraordinarily valuable research results are now emerging on how complex biological soil-plant systems and human pathogens interact. Food safety would be impossible without the protective role played by microbial soil ecology; and ways to cooperate with this complex system, rather than against it, will necessarily become foundational to enhancing the safety of food.

Additional information: Testimony to the USDA hearing, follows.

TESTIMONY OF TOM WILLEY, OWNER, T & D WILLEY FARMS, Madera, California at the hearing on the proposed National Leafy Green Marketing Agreement, Monterey, California.

My wife and I own and operate a 75-acre, certified organic truck farm just outside of Madera in the central San Joaquin Valley. We grow over fifty vegetable crops, including many in the leafy green category, farming the year round to supply West Coast specialty retailers, restaurants and our own local subscriber network of 800 families who are members of T & D Willey Farms CSA. I've spent most of our farm's near 30-year history pursuing the knowledge and art of biologically intensive soil management in an effort to gain a reputation for the most tasteful and nutritious produce in the marketplace. I am proud to boast a handful of my soil harbors nearly six billion living microbial organisms of vast diversity, equal to the number of human beings inhabiting earth, which generously power the fertility cycle upon which we all depend for our very lives. Eschewing toxic inputs while relying only on biological processes to grow high quality, high yield vegetable crops is a stimulating intellectual and scientific challenge for which I and my customers have been well rewarded. I'm afraid some significant problems in food safety and misguided approaches to their solution, like NLGMA, could derail achievements in biological agriculture and a greater promise of food made safe through respect for and cooperation with the microbial community which owns and operates this planet upon which we are merely guests. The antibiotic resistant and increasingly virulent organisms contaminating our produce from time to time are mutant creatures introduced into the larger environment from confined industrial animal operations across the American countryside. CAFO's using as much as 70% of the nation's annual antibiotic supply in subtherapeutic feeding regimes to mitigate crowding, stress and unnatural diets have been documented by the Pew Commission on Industrial Farm Animal Production to have created at least several of the very dangerous pathogens which episodically threaten today's produce supply. This commission's membership includes such environmental wackos as Dan Glickman, former USDA secretary of Agriculture and John Curlin, former Kansas Governor. Why our vegetable industry refuses to throw rocks at the glass house of industrial animal production is beyond me to comprehend. Instead we pretend it is possible to superimpose a paradigm of sterility over vegetable farms by implementing the more extreme practices suggested by LGMA or rogue buyers and processors to mollify an ignorant and nervous public. If animal manures were an inherently dangerous agricultural input, the human race would have long since become extinct; instead its judicious use has remained a hallmark of good fertility management for centuries if not millennia. If manure is now uniquely dangerous, we must investigate why and rectify it or prepare to pack animal waste into space capsules for rocketing to the moon. The cornerstone of my farm's fertility program is thermophilically digested composts from both dairy cows and urban green materials. These are produced to rigorous NOP standards and regularly tested for the absence of human pathogens. Robust and diverse soil microbial communities, enhanced by additions of quality composts, have been demonstrated to be less friendly environments for human pathogens by excluding or more quickly eliminating them.

There is no recognition given this proven strategy in LGMA metrics, on the contrary a great pall is cast over the use of manure or compost that would frighten your average grower to death. We test our water for human pathogens and impose worker sanitation protocols but I refuse to soak my produce in chlorine or ozone baths out of respect for a healthy association people require with soil life for digestion, nutrient absorption and healthy immune function. Besides, disrupted microbial ecologies, even on leaf surfaces, offer greater colonization opportunity for pathogens, also completely unrecognized in LGMA metrics. So in short, I do not wish to join the club, which I'm told is my sole prerogative. But LGMA competitors, pursuing sterility, will sport a USDA approved seal suggesting their produce is safer than mine when the opposite could very well be true. I've already lost my Canadian accounts as that nation's government, in ignorance, prohibits imports of leafy produce not signatory to the current LGMA. The alternative potential of unleashing moon-suited FDA squads over vegetable farms may be less palatable than a privately regulated LGMA under Department of Agriculture authority. However, I cannot personally endorse an approach to produce safety which is essentially a marketing gimmick, as is the LGMA scheme. Our entire society must take more responsibility for the quality and safety of the food we eat. Much more publicly funded research and education will be required to forward greater food safety in our over-industrialized cheap-food system. Fortunately the National Institutes of Health has recently launched a five-year research initiative, the Human Microbiome Project, to uncover the complex relationships our species enjoys with cohabiting microbes enhancing human health. On and within the body of a healthy adult, living microbial cells outnumber human cells by a factor of ten to one. The human body is more properly described as an ecosystem, hosting trillions of microbial hitchhikers in elegant symbiosis. I've dedicated my farming career to the enhancement of these interspecies relationships through the food I grow for my customers. Misguided approaches to food safety arising from an atmosphere of hysteria and ignorance threaten to disrupt the genuine advances this nation requires to improve its food and our citizens' health.

Interview with Will Daniels and Samantha Cabaluna, Earthbound Farm. Daniel B. Cohen, Maccabee Seed Company, July 17, 2013.

Earthbound Farm (EB) is one of the largest California leafy-green fresh-cut processors.

Will Daniels is VP for Quality, Food Safety and Organic Integrity for Earthbound Farm He is a board member of the California Leafy Green Handlers Marketing Agreement (CA LGMA) Samantha Cabaluna is VP of Communications and Marketing for Earthbound Farm.

EB uses safety practices that go beyond the CA LGMA as well as meeting their requirements and metrics as member handlers. Will Daniels' experience at EB gives him a different perspective from the LGMA on some food safety issues.

For example, EB tests water and other inputs for pathogens of public health concern. They do not rely on tests for indicator organisms (see below).

EB has a comprehensive food safety program that goes from planting through processing to delivery to consumers. It is a data and validation driven program. They want their food safety programs to be proven to work; they test and validate methodology first, follow the validated protocols, and document what they have done. They also do research on new methods.

They were the first fresh-cut company to institute 'test and hold'. Seven years ago they consulted with microbiologists to design statistically valid programs for detection. Produce is held and tested before entering the plant, and finished product is tested and held before shipping.

When averaged over the course of the year, about 3000 lbs of produce are rejected weekly before entry into the plant, and about 600 lbs are rejected as finished product before shipping, out of 2.5 million lbs produced..

The marginal cost for this is about 3 cents a bag (or equivalent unit) for testing, additional personnel, and the company's scientific advisory panel.

They tested planting seeds of their vegetable crops for human pathogens for five years, which made the American Seed Trade Association less than pleased. They stopped testing after finding no human pathogens consistently the entire time.

They require a process authority validation for all fertility inputs and test all water sources and fertility inputs for specific pathogens of public health concern (in addition to LGMA requirements).

They have worked with fertilizer suppliers for organic farms over the years including producers of liquids, pelleted chicken manure, composts and other products. The

suppliers came from an unregulated background where they did not necessarily see themselves as part of the food safety chain.

EB uses composts, and tests for human pathogens. With regard specifically to windrow composting, they are still trying to validate a methodology that will deliver consistent safe results. When they go to visit compost suppliers they sometimes see problems in testing methodology. Will Daniels mentioned sufficient high temperature uniformly through the pile to control pathogens but did not mention the proliferation of beneficial micro-organisms during curing (cooling). Since beneficials are supposed to supply control in formation of mature compost, protect against recontamination, and increase the safety of compost over time it was a little surprising he did not mention they were trying to validate this part of compost-making. In a later comment he said:

“Beneficial bacteria are part of the process but what we are doing is specifically testing for the presence of pathogenic bacteria. If the beneficial bacteria are doing the good work, then the pathogens won’t be present.”

Additional information can be found in two articles following Will Daniels’ talk at the Food Safety Summit in Baltimore in May 2013: Coral Beach’s article in The Packer (05/01/2013) and Sangita Viswanathan’s article in FoodSafety Tech (05/09/303). Points to add here are that EB is willing to be open about its food safety procedures with other processors and researchers, does not believe that food safety should be a point of competition, and that buyers (retail chains, food service) are primarily incentivized on price, which doesn’t leave much leeway for compensating suppliers for enhanced food safety programs. .

EB has issues with the proposed rule.

Water.

Will Daniels opposes using a ‘generic for E. coli’ indicator metric for water quality testing. He says one has to test for the pathogens themselves. Even testing for O157:H7 (within E. coli) is not enough. You have to test for the emerging STEC and EHEC strains as well.

They participated with the Pew Charitable Trusts (Pew) initiatives on food safety, and support Trevor Suslow’s position in the water quality review paper for Pew. Generic for E. coli levls are completely uncorrelated with human pathogens such as O157:H7 and

salmonella. Generic for E. coli levels can be high and human pathogen levels low; human pathogen levels can be high and water can pass the generic for E. coli action levels in the LGMA, which are the same as proposed by FSMA.

They have six years worth of data on this and other metrics and are preparing data to submit to the FDA during the comment period of the proposed produce rule.

The actual sampling protocols proposed in FSMA for surface waters such as rivers and irrigation canals at point of entry into a farm are inadequate, no matter what the standard. Changes in pathogen levels can be intermittent and transient. To really test moving waters one would have to have continuous monitoring.

How much of this should be governmental responsibility, that irrigation districts and surface waters used for irrigation should arrive at the farm safe for irrigation? That would be ideal but you have to live with the reality as it exists now. Right now he would settle for irrigation districts and other agencies to just not dredge or do other work that releases pathogens when it is the middle of the growing season.

They have worked with fertilizer suppliers for organic farms over the years including producers of liquids, pelleted chicken manure, composts and other products. The suppliers came from an unregulated background where they did not see themselves as part of the food safety chain.

Fertilizer

Sewage sludge has no place in fresh produce production. It is not needed, and has issues beyond those mentioned for Class A EPA sewage sludge ratings for human pathogens, which is allowed by the EPA for produce production under highly restricted conditions. [These include heavy metal content, pesticides, other chemicals, drugs, their breakdown products and their chemical transformations in interaction-- dbc]. Leaving this uncovered leaves produce vulnerable to both consumer rejection, when they learn about it, [to the testing regimes and goodwill of sludge producers -- dbc] and allows foreign producers to use sewage sludge as well, which may not meet the actual EPA restrictive conditions.

On applications of composts and manures, or their timing, which differ between the FDA proposed rules and the USDA's organic production rules (and other regulations), they all should at least be on the same page .

What about cleaning up human pathogens at the points of constant entry, where possible such as in dairy herds, large confined animal facilities (CAFO's), large high density confined poultry production and others?

The larger answer would come from looking at how to have a healthy ecology for animals, plants and humans (see below). On human pathogen free herds, EB is specifically looking at research on feeds that would eliminate human pathogens in

poultry, cutting off a point of entry into the farming ecosystems. (but this is something we are tracking through our scientific advisory panel – we are not conducting the research ourselves.)

Habitats and the farm environment

Will Daniels has a very different view than most of the processing industry and large buyers: that there is a positive role for farm habitat and that biological complexity is promoting food safety, not endangering it.

The environmental destruction of farm habitat in the Salinas Valley and elsewhere that followed the followed the 2006 spinach O157:H7 outbreak was a knee-jerk reaction. The general attitude of trying to create sterile environments on-farm and in the landscape surrounding farms actually creates greater pathogen danger.

What really happens when you eliminate habitat surrounding farms is you invite animals into the production fields.

Therefore you have to protect habitats surrounding rivers and creeks and streams. If a waterway goes through or borders a farm, a habitat buffer that keeps animals without the need to enter farms should be maintained. You evaluate it as a potential risk, and take actions based on actual observations when hazards (intrusion into the field) occurs. Then you take reasonable procedures to protect against that hazard based on the specific risks.

He sees the Colorado river system as a biodiverse water system that is largely free of human pathogens.

What really happens when you consider fish, ducks and plants to be hazards in an irrigation pond and turn it into a lined, sterile-looking container is that you create a petri dish for human pathogen increase.

In contrast, EB takes the approach that biodiversity and ecosystem health provides the best systemic background for exercising human pathogen control.

They differ with the proposed rule in seeing balanced healthy ecosystems as promoting food safety not impeding food safety.

Fresh-cut

I had to preface this question with an apology for even asking him: do you consider fresh-cut to be a unique category of production and processing with its own specific hazards and requirements?

Yes. There is no kill step. This makes fresh-cut processing different from most food processing where there is a kill step.

Regulating fresh-cut produce

EB's position is that since fresh-cut is covered under the proposed Facilities Rule ("FSMA Proposed Rule for Preventive Controls for Human Food Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food") which requires HACCP with individual analysis of each firm's hazards, this is adequate. The hazards of fresh-cut go all the way back to the farming practices, so the processors would have to account for the particular issues of their farm-suppliers as well.

Therefore he did not see a reason to cover specific farming practices for fresh-cut under the proposed Produce rule, as there is for sprouts.

Human pathogen contamination of produce in farming, before harvest.

Will Daniels noted that

"I drive the farmers crazy when I say this, but I think most contamination happens on-farm <u>most</u> of the time."

They conduct tracebacks on all lots that test positive, and I asked what their records show about this.

He said that out of about 1,000 positive lots, they only could find the pathogen source in 7 cases.

Since these represent the kind of effort that goes into an FDA major recall followed by an environmental investigation --- which are very rare -- I asked what these 7 cases showed?

He mentioned three cases: (1) an overflow reservoir became contaminated and was cross-connected with an irrigation system, (2) compost was a contaminated source and (3) fertilization off-season may have contributed to contamination of produce.

I did not ask whether they matched the particular strain of pathogen to the pathogen in the rejected produce, as would be done for an outbreak investigation, because that is not the objective of their system of controls. – We do match them.

In a follow-up, Samantha Cabaluna noted that no tracebacks found post-harvest contamination from harvest to intake: for example in washing/rinsing on farm, packing and trucking to the EF loading dock.

Structure of the proposed Rule

EB agrees with other major produce industry groups on several problems in the structure of the proposed Rule. The main problem is that setting metrics into the rule would create unmanageable regulatory inflexibility. They favor putting metrics into Guidances instead, which can be changed as data comes in and new techniques are developed.

As mentioned above, they agree with many large players in the produce industry that fresh-cut does not require its own specialized farming rules under the produce Rule. They disagree about what should be measured, and as mentioned above, EB only supports measuring the actual human pathogens of concern.

Alternative to the proposed Rule

Will Daniels would use a three sentence regulation, with one supplemental sentence. He has expressed this several different ways but it would go something like this:

(1) Every operator and farmer has to do a specific risk assessment of how their operation will affect food safety to the consumer.

(2) They have to design a control plan to mitigate these risks and validate that their plan works.

(3) They have to follow the plan and verify that they are following the plan by documenting it.

(4) Other aspects of the Rule should only be given in Guidances.

Here is how Samantha Cabaluna expressed it in a follow-up:

“Perform a risk assessment of your product in your system; understanding their use at the consumer level (washed, eaten raw, in a bag, open, etc.). Create a plan that mitigates those risks and validate them. Verify control through documentation.”

Will prefers this to the numbered statements above.

Scale-neutral Risk Reduction

Processors are required to use HACCP (hazard analysis of critical control points) and other measures to control food safety. Others need to do a reasonable assessment of risk and controls.

EB strongly supports small farms and others to use the free food safety risk assessment tool developed by Family Farmed (dot) org, recommended by the USDA. Even someone who knows little about food safety issues can be guided through a step

by step program, with educational materials included as needed. At the end the safety program and all the documentation forms needed to verify it are created.

Will Daniels has seen a small farmer use this as the sole tool for implementing food safety, and pass a USDA GAP certification (good agricultural practices standards for their production).

He says even a large processor could use the same tool and it is effectively scale neutral.
Samantha Cabaluna, in a follow-up noted:

“Will got involved early with FamilyFarmed.org as they were talking about developing a manual to help guide farmers through food safety plans. Will suggested that if they could actually develop an online tool that would produce a plan in the end that the farmer could be audited against, it would be great. So Will recruited several industry experts from FDA, Western Growers, United Fresh Produce Association, Produce Marketing Association, Community Alliance with Family Farmers, & Wild Farm Alliance and they all worked together to create the content for this tool, which launched just over a year ago. The idea was to include everyone in the conversation as many felt left out of the LGMA metric discussion.”

Conclusions

At the end of the day, each region is different with its own climate and soils and challenges, and each farm is different, with a unique production system. Risk assessment has to be made for each farm, and a ‘one size fits all approach’ such as the proposed rule, will never work. One size does not fit all.

Statement of Jo Ann Baumgartner, Wild Farm Alliance, July 13, 2013

Jo Ann Baumgartner of Wild Farm Alliance is based in the Salinas Valley of California. The Salinas Valley is the heart of the "salad bowl of the United States" and has faced the consequences of rules like those in the FDA's proposed Rules. One could say that the experiences in this region are a prelude to, and a forecast of, what could happen to farms all over the country depending on how the rules are finally written.

She is probably the most experienced person in the country on working with farmers to allow farming to co-exist with, and be a benefit to, the natural environment. One double-bind for farmers, that she does not mention below, is that the Salinas Valley drains into the Monterey Bay Marine Sanctuary, the "Serengheti of the Sea" and the largest such sanctuary in the United States. Buffer strips and grassed-canal banks and other ecological features of farming helped farmers avoid EPA imposed sanctions against fertilizer and pesticide run-off , by filtering them and allowing for recycling of nutrients and decomposition of pesticides. When farmers were asked to choose between having buyers for their produce or ripping up farm habitat, they also put their EPA compliance at risk.

Jo Ann will probably make her own extensive and knowledgeable comments to the rule. She prepared the following statement, which is presented here instead of using my interview notes.

Ensuring the Rule Contains Language for Conservation Protections

After the 2006 E. coli O157:H7 spinach contamination, a survey conducted by the Resource Conservation District of Monterey County in 2007 found 89% of growers, who managed 140,000 acres along the Central Coast of CA were destroying wildlife and their habitat. The growers reported being forced by their buyers to choose between selling their crop and following misguided food safety recommendations targeted at removing wildlife. Suddenly growers who had been participating in programs that protected water quality and supported beneficial insects and wildlife were taking out conservation plantings or refusing to install new ones.

Conservation-minded farmers who valued wildlife were put in an untenable position. In a meeting I attended, one such farmer described how it was becoming common practice to poison frogs -- this in an area of California where some of these frogs could have been protected red-legged frogs. Some of the destruction was blatant -- a 20 acre lake was bulldozed right next to a major highway. Some more on the sly -- one mile of Salinas river habitat, tucked into agriculture's outback, was removed; big trees bulldozed into piles so the habitat would not be close to the salad-mix fields.

Conservation practices provide many public benefits -- they can filter out pathogens and other pollutants, support predatory pest control organisms, and ensure the biological diversity of our landscapes stay intact.

As written in the preamble of FDA's proposed produce rule, the presence of wildlife on the farm, in and of itself, is not a significant risk. This is borne out in research that shows the risk of wildlife causing a widespread food safety outbreak is low. However, there are still farmers in the Salinas Valley whose buyers refuse to accept their crops because of adjacent conservation practices and habitat. SInce there is no governmental control of buyer requirements, FDA must give clear direction in the produce rule. Many of FDA's comments about wildlife and conservation, buried in the preamble, must come to light in the actual rule, including the following:

-- When appropriate, farmers should use sustainable conservation practices that benefit food safety.

-- Wildlife, in and of itself, is not a significant risk. If large numbers of wildlife, signs of their feeding, or their feces are found in the produce field and deemed a significant risk, steps taken to reduce that risk should not include removing wildlife habitat or conservation plantings. If fencing is used, it should only exclude the animal of concern (example: using pig fencing to keep out feral pigs) and should not be used as an excuse to fence out all wildlife.

Comments by Dave Runsten, July 2013. To Daniel B. Cohen, Maccabee Seed Company.

Dave Runsten is the Policy Director at the Community Alliance with Family Farmers (CAFF) with its main office in Yolo County California. Before that he worked at UCLA in the Public Policy School. He studied economics at Stanford and Berkeley and has worked on food safety issues of family farms for over seven years. He has great expertise in the legal and economic twists and turns of produce safety in California, from the impact on large producers in the CA LGMA to small or new organic farms.

At CAFF, we believe that everyone needs a food safety plan, but it should be appropriate to the scale and risks of the farm. We have a program that helps farmers develop such food safety plans for their farms and then pass GAPs audits. We would be very happy if the FDA required some basic GAPs and then provided guidance on crops of particular concern.

A number of people have pointed out that the FDA did a poor job of reviewing relevant literature. It is hard to have confidence in their conclusions. And just because some experiment showed pathogens can survive for a long time does that mean they will? And that people will get sick?

I think the overarching problem is the tendency, driven by litigation, to require everyone to engage in costly and questionable preventive controls even when the risks are quite low. "The only acceptable risk is zero risk" is the mantra of the consumer groups, the food retailers, the food service corporations. One of the problems I see in this rule making is that there are no data about how risks might be lower in smaller organic systems, and in fact there seems to be a bias at FDA against such systems. So all of the rules are made for large operations and then applied to everyone else." (email July 06 2013)

The proposed Rule follows along with the approach started by the CA LGMA (California Leafy Green Handlers Marketing Agreement). To some extent the LGMA was an improvement on the rules that were being imposed by the largest end users and buyers after the spinach crisis (2006), the so-called "super metrics." At least there is a mechanism for science, research and facts to influence the regulations and metrics under the LGMA.

However there still are separate buyers' contracts, in Salinas and elsewhere, and some of these contain non-disclosure clauses so their consequences and relationship to LGMA rules cannot be evaluated by others.

One of the problems is that no-one actually wants to pay anything extra for produce safety. The large buyers told the large handlers "follow these rules or we won't buy from you." The large handlers told the growers "follow their rules or we can't buy from you because we can't sell your produce to the large buyers." The LGMA codified the

handlers' power to make uniform rules for farmers. This more or less was satisfactory to the larger buyers and the general produce trade. Farmers were at the end of the line and had to take whatever losses the additional practices imposed. Even some large farmers were not happy, either about the science supposedly behind the on-farm regulation, or being told what practices they had to follow without any compensation. When we first got involved, whole fields were being rejected for arbitrary reasons such as some animal intrusion, and false positive tests were causing a lot of produce to be destroyed.

Western Growers and other major industry groups oppose having detailed metrics within the proposed rules and final rules themselves. They want to preserve flexibility, and modifying a federal regulation is a lot more onerous than changing, say, an FDA Guidance document.

The five possible pathways of contamination defined in the proposed rule are pretty much the ones anyone would come up with [except Cohen]: water, soil amendments, animals, worker health and hygiene, and contact surfaces. The problem is how these subjects are treated. For example the generic E. coli standard for water has been shown to be a waste of time; it is not correlated with the pathogenic E. coli and seems to us to be more about public relations than anything else. Maybe you test the water a couple of times a year, but weekly? Forever? There is going to be a lot of opposition from major commodity groups that have not been under an LGMA-like rule in the past.

The FDA was forced to consider composting as a treatment method by the explicit language of the law but they are still pretty resistant to the notion. There is a lot of mythology in the concerns about food safety, one is that manures are used only in organic farming. Some of the older farmers think the industry may have introduced human pathogens into the Salinas environment when they started hauling dairy manure from the San Joaquin Valley into the Salinas Valley for conventional farming years ago. If all farmers, conventional and organic, followed the compost and animal manure rules in the federal NOP there would be a great increase in food safety.

The FDA was also forced to consider modifying the regulations for smaller farm sizes by the Tester Amendment which became the language of the law. This doesn't exempt the farms from food safety practices, because ultimately no one is going to insure you if you don't have a food safety plan. But it alleviates the costs of regulatory compliance by smaller farms with rules that were originally designed for some of the largest farmers in the country, and which these largest farms can afford to comply with.

There is actually a different issue about farm size: some of the practices smaller farmers use may be safer than the practices on the largest farms. I'm thinking about hand harvesting of leafy greens and other produce vs. instances where on a large scale you use a mechanized harvest. One reason to be paranoid about frogs and other small animals is the mechanized harvests are much more likely to include them in the salad mix. The consumers really don't like seeing this in the bag and the lawyers for the processors really don't like having to defend against a frog in a salad bag. So legal

concerns derived from mechanized harvest sometimes masquerade as food safety concerns about pathogens.

But a hand harvest, although more expensive, is different. If food safety were really the number one priority, you would probably ban all mechanized harvest as a safety measure! That's not going to happen.

But the FDA could have accounted for this in the proposed rules; or researchers could actually try and measure the differences in outcomes first. That's just one example of how large scale itself may be a hazard that some smaller, less mechanized farms do not face or, in other cases, may not face but not enough is really known. There are no data!

There are other reasons why truly local food may be less risky: there is less time between harvest and consumption, for example, and less time for pathogen growth and multiplication. With local food there is less centralized processing with potential cross-contamination of very large production runs that are then nationally distributed. These are only factors of reduced over-all risk but they are real and unaccounted for in the proposed Rule.

On the other hand I get in trouble with some organic and local growers when I tell them they may have to change their practices for food safety. They don't understand why they can't just keep doing what they have done in the past. I have to tell them that they are dealing with a more polluted environment, including the farm environment. Some of the pathogens have changed and mutated and are more deadly or spread through animals they were never associated with in the past. It is an unfortunate fact of life that we are farming in an increasingly polluted environment and the FDA is doing nothing to change that.

Furthermore, you can be a regional organic farmer and still cause an outbreak and recall from selling your bagged fresh-cut salad mix, we know of at least one case. So when you take on an additional risk like producing bagged fresh-cut produce, you better know what you are doing. The insurance companies will catch up to them. Farmers tell me it is already hard to get insurance if you produce leafy greens and are not part of the LGMA in California.

There are some Ironies about the fresh-cut industry being regulated now as processors under the proposed processing rule [FSMA Proposed Rule for Preventive Controls for Human Food, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food] because they are no longer considered producers of raw agricultural commodities. For many of the early years of fresh cut they did not want to be considered processors of any kind, they wanted to be considered "packers" or "handlers" because all they were doing was packing raw agricultural commodities.

The FDA and USDA still have trouble recognizing fresh-cut as a unique processing industry for produce. [I mentioned to Dave that that the Produce Rule categorically

excludes fresh-cut, while the processing rule does not recognize fresh-cut as a category of specialized risk or even specifically mention it!]. We showed it was responsible for 90% of the outbreak-caused illnesses in produce due to O157:H7 and similar STEC E. coli. [That has not changed]. But it got harder and harder to get outbreak investigation reports except for the largest national cases. Our FOIA request was a waste of time. The FDA didn't even distinguish fresh cut before 2000.

We have been saying for years that there has to be some recognition of the role of CAFOs (concentrated animal feeding operations) in overall produce safety. Individual farms are downstream [literally and figuratively] of CAFOs pumping increasingly risky pathogens into the farm environment. All of the burden is placed on individual farm operations growing produce to fend off pathogens created by entirely different animal industries. Systemic risk beyond farmers' control should also be addressed in a proposed produce safety rule.

Finally, from an economics perspective a "qualitative assessment of risk" is an oxymoronic phrase. Risk means that you know what the probabilities are and can quantify, anything else is just uncertainty. The FDA is uncertain! They don't have the data! They shouldn't be writing these rules without the data. And the so-called economic impact assessment is even worse. They should have hired farmers to help them get the numbers right. There is a lot that is wrong in the proposed Rules.

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July 22, 2013 — Perishable Pundit

http://www.perishablepundit.com/index.php?date=07/22/2013#7

Pundit's Mailbag – The End Of The Yeoman Farmer? Does Society Care Enough About PTI And FSMA To Put The Small Farmer Out Of Business?

...The obvious dilemma on food safety regulation of all types in produce is that since this is not a yes/no question, "is the milk pasteurized or is it not," we are always talking about a series of practices that are believed to enhance food safety — more frequent water testing, more traps per acre, etc.

Since there are no particular amounts of these practices that produce "safe food," we are talking about setting some level for each of these things. We can do this nationally or we can we can require site-by-site food safety plans but, in any case, this is at least as much a hunch as it is science, and the benefit derived is most uncertain.

The problem is that food is so colossally safe that an effective intervention — say one that God came down and told us would, in fact, somehow reduce mortality from leafy green consumption by 5% over the next century — is, in fact, impossible for humans to divine from any known data source.

The incidences of food safety problems generally are wildly unpredictable Black Swan events today, and so the fact that we require say a weekly water test and then have no food safety incidents for five years does not mean that the next year can't be the worst year on record.

This colors the discussion of application of food safety standards to smaller farms because, in fact, we don't know very much about the effectiveness of many of these regulations. There was no controlled test in which some producers were PTI-complaint and some were FSMA-compliant and some were not, and we can thus say with confidence that any of these things save lives or reduce illness.

In general, as a matter of commercial fairness, we would say that if a policy is important enough to impose on growers, it has to be imposed on all growers. Otherwise we start distorting the market, leaving people to organize themselves inefficiently in order to avoid certain regulations.

In addition, a primary benefit of government regulation would normally be an increase in public confidence of food safety, which will increase willingness to purchase, but this benefit won't come about if the regulation does not apply to everyone and if consumers have no way of knowing if the tomato on their sandwich was grown under the regulatory regime or not.

Beyond this, uniform regulation serves to reduce transaction costs and thus makes for a more efficient economy. If anyone can buy from any grower, shipper, wholesaler, etc., and know that all product is compliant, it saves a lot of cost and encourages small business because small businesses are the ones having the most trouble ensuring product is complaint.

This last point may somewhat outweigh the obvious problem, which is that compliance can burden small growers. If a water test is prudent every 24 hours, that will cost a two-acre farm much more per acre than a thousand-acre farm. Because the paperwork burden is not dissimilar whether one is ordering a bag of a soil amendment or a thousand bags, compliance, which includes being able to document compliance, is going to always burden small businesses more than large ones and, in this case, small farms more than large farms.

Yet, this all may be somewhat academic. Large buyers such as Wal-Mart have multiple interests, food safety being just one of them, and this mirrors society at large. The reason an exemption for small farmers was put into the FSMA, over the objection of United and PMA and WGA, is because as important as food safety is, it is neither the only concern nor the highest priority.

It may seem shocking to say that food safety is not the highest priority when everyone always says it is. It is not that these people are insincere; it is just that we are talking about infinitesimally incremental actions that are hoped to have some impact on food safety.

We are not certain that government regulation, in general, actually encourages food safety. We suspect it encourages an attitude of complacency that may well inhibit food safety. The government's implied warranty that everything is safe makes it difficult to receive a good return on investment for safety efforts that exceed government requirements and, by the nature of democracies, it is difficult for governments to require world class standards.

Still, this is the way of the world, and so we have government-dictated food safety standards, but we also see little evidence that our representatives have the stomach to cause mass bankruptcies. This is why, despite the government report in the aftermath of the Jensen Farms cantaloupe situation, clearly stating that pre-cooling is important for food safety, that nobody is banning the sale of non-pre-cooled cantaloupes.

For a long time now, many produce industry companies have signed affidavits necessary to get business — then they did their best to produce safe food within the budget allowed and their own capabilities. If there was ever a real problem, they prayed for a fire to burn all the records.

There is some possibility of a bifurcation of the trade with independents buying non-complaint product and large chains paying up for PTI— and FSMA-compliant product, but competitive realities being what they are, we suspect there will be continuing pressure to expand loopholes and that exceptions will be allowed in the name of organic, local, small-scale, artisan or whatever the sentimental favorite is at the moment

APPENDIX A (Section I, Farming-caused outbreak data)

"There also has been a systemic bias in outbreak investigations and reports to find exculpatory excuses for processors. This goes all the way back to the first reports of O157:H7 on in apple juice from the early 1990's."

The bias may be understandable, because in some key outbreaks the processors were using the best or newest technology available at the time an outbreak occurred. They were the "good processors" who took food safety seriously. But it is not particularly helpful for understanding the outbreak record: when farming practices determine an outbreak occurring, or whether an outbreak's extent and damages to human health were determined by farming practices or processor practices

When I have looked at final investigation reports from CFSAN (FDA), outbreak investigations from states such as California, Minnesota, Oregon and Colorado, and the CDC's final reports on outbreaks, one finds three problems with assigning causation to farming practices even in highly probable cases:

(1) There are documented failures in the post-harvest processing such as maintaining sanitizing effectiveness of chemicals in wash-water in fresh-cut spinach and apple juice.

(2) failure to find an outbreak strain within a processing facility may only indicate the relative ease of sanitizing processing equipment or facility water sources before inspection and

(3) facilities, processing steps, or produce could have been directly contaminated by a pathogen source in the farm environment.

For example: systemic and persistent pathogenic Listeria contamination of a packing facility itself with multiple outbreak strains was concluded to be the basis of the 2011 cantaloupe outbreak. There were plenty of other Listeria found in the surrounding farms and environment, many non-pathogenic and some pathogenic but not the outbreak strains. Some of the processing equipment was un-cleanable, which helped with the outbreak investigation but also contributed directly to the outbreak.

One can do a thought experiment: what if, during the 2011 Listeria cantaloupe outbreak, equipment, floors and other facility sources had been fully sanitizable and sanitized before investigation? The investigation report would read something like this: "No outbreak strains or Listeria were found in the handling facility. Non-outbreak strains of Listeria were found, however on farm and in the farm environment. Contamination from the farm cannot be ruled out."

Except for the first sentence, that's how the actual final investigations read.

Accidental contamination of produce that is delivered to handlers and processors should be expected to happen, whatever the original source and immediate cause of such contamination, and one would think that the routine procedures of processors, at least, should be able to handle such events by detection/exclusion, treatment during processing and testing before shipping. This was not the case in the past, and the record of recalls suggests it is still not the case.

In a May interview, Will Daniels of Earthbound Farms described his company's practices that do include holding and testing incoming produce, thorough process controls in the plant and holding and testing before shipping bagged produce as well as on-farm controls and testing. The total cost for much higher produce safety was 3 cents per unit (such as a bag of organic fresh-cut leafy greens).

Let me suggest that this is not entirely a problem of farming practices.

Furthermore, an environmental source of human pathogens may be naturalized and persistent, or introduced and persistently re-introduced. In the latter case, controlling pathogen re-introduction would better solve food safety issues. The source of an outbreak contamination can have a preventable cause itself.

The lack of data is emphasized in part, but only part, of the "Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce" (the "QAR") and the significance of this lack of on-farm causation data was ignored in the "Analysis of Impacts -- Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption" (the "Economic Analysis"). These two documents are the foundation for the justification of the entire proposed Rule; the QAR is the science-based review required under the FSMA and the Economic Analysis is the required economic impact analysis.

For this, and other reasons, the outbreak data used in the QAR (from 1996 - 2010) is nearly useless for analyzing farming-practices caused produce outbreaks.

There is a problem with looking at outbreak data uncritically. Until quite recently the finding of non-outbreak strains of a pathogen in part of the farm environment, deer feces for example, would have been sufficient to assign a probable source of the outbreak. This was true in 1996 when older means of pathogen strain identification identified the outbreak strain of E. coli O157:H7 in both an unopened bottle of Odwalla juice. Dan Flynn from Food Safety News summarized the multiple findings as follows, thirteen years later, in 2009:

"...investigators from FDA did find numerous violations of health and safety codes at the Odwalla manufacturing plant, including lack of proper sanitizing procedures and poor employee hygiene. The FDA also found that the plant accepted decayed fruit from suppliers.

"The investigation was ultimately expanded to include inspection of apple orchards, produce suppliers, and packinghouses that furnished the central California plant with the apples. None were implicated as the source of the contaminated produce."

(http://www.foodsafetynews.com/2009/09/meaningful-outbreak-4-odwalla-apple-juice-e-coli-o157h7-outbreak/#.UeQuAr871z9)

But in 1996 non-outbreak strains of E. coli O157:H7 were found in deer feces and deer were assigned the role as probable source of the outbreak strain as well. The most common assignment of outbreak causation at the time was that deer feces contaminated downed apples (which were then waxed, which didn't help) because non-outbreak strains were found in deer feces. The reality seems more complex.

Increasingly sophisticated and ever cheaper DNA marker techniques, genomics, and whole genome sequencing are slowly changing these kinds of conclusions from outbreak investigations. If I had to pick a rough cut-off point, the beginning of increasingly sophisticated analysis as routine in major cases, it would be the 2006 fresh-cut O157:H7 spinach outbreak. The increasing ease of specific pathogen strain identification changed the ways inferences are made. Finding a pathogenic but non-outbreak strain was no longer indicative of finding the probable source of an outbreak.

The STEC E. coli O145 on packaged shredded lettuce environmental assessment investigation report is an excellent example of post-outbreak thorough investigation (Crawford, Baloch and Gerrity, 2010) and is also mentioned in documents supporting the proposed Rule. The final CDC report update was on May, 21 2010, titled "Multistate Outbreak of Human E. coli O145 Infections Linked to Shredded Romaine Lettuce from a Single Processing Facility." This is an outbreak that shows up in the databases used for the proposed Rule. Briefly, one can note that the most likely sources of contamination were human pollution sites located near the irrigation district canal that fed to the irrigation system of the sole farm source of the contaminated batch. The outbreak was possibly affected by unusual weather events as well. "Subsequent laboratory investigations of romaine lettuce showed at least intermittent contamination on later production days from the processor and triggered preemptive recalls of initially a single contaminated lot, and then all production from the implicated farm." (CDC). Better watershed surveillance and public health investigations aimed at preventing future contamination are not under farm control. The Ohio processor's test and hold procedures before entry and product sampling are not mentioned.

If one analyzes this case critically, it is difficult to call it just "on-farm contamination". It combines a public health issue in a public water delivery system as well as a high risk processing category, fresh-cut, and unknown processor product controls of a high risk category. It is an example of pre-harvest contamination, and appears to be noted as such in the CDC statistical records.
[end of Appendix A]

APPENDIX B (Section I, Mis-using CDC and FDA data to justify on-farm regulation)

Lacking on-farm data from FDA outbreak recalls and CDC investigations, the QAR and the Economic Impact documents are systematically misleading in their use of CDC epidemiological records. In my view they stop just about a hairs breadth from outright deception. What they do, in effect, is project back on farming all the consequences of produce-associated food-borne illnesses irregardless of where contamination occurred. The QAR looks at CDC data from 1973 - 1997 and discusses "produce associated outbreaks". One might expect that in a farming Rule this meant outbreaks due to on-farm sources, but of course that is not the case -- especially with this date range when even the form of a produce commodity was usually not identified, something that has only slowly been recognized as important. But these are all illnesses associated with produce.

The QAR then adds FDA outbreak surveillance data from 1996 - 2010, based on CDC data but without intrastate outbreaks, person-to-person transmission or "where the source of contamination was likely in the home or at a retail setting." But this breaks down as they increasingly use total illnesses regardless of point of contamination.

The entire discussion of health effects, and costs, of illnesses due to farming practices is expanded from farming, harvest and initial preparing for market to every point of contamination up to the point of consumption. All the statistics on illnesses, hospitalizations and deaths, first by disease agent, then by produce commodity, and then by produce commodity and disease, are nearly worthless for understanding the actual points of contamination and the relative roles of farming practices, processing practices, and other steps for delivery to home or to retail.

The QAR then makes the below statement and refers to the "Economic Analysis" for further details:

"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."

Yet here is their own Table 13 in the Economic Analysis. RAC means raw agricultural commodities, which are the only produce covered under the proposed rule as it stands. Fresh-cut is not included. (Refer to page 59 of the draft QAR or mentally shift the summation numbers at the bottom by one column over to the right)

Table 13. FDA Outbreak Data for Illnesses Attributed to RACs Other Than Sprouts, 2003-2008 **Commodity**	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Berries	*Cyclospora*	1	59	2	0
Herbs	*Cyclospora*	3	678	1	0
Leafy Greens	*Cyclospora*	1	38	0	0
Peas	*Cyclospora*	1	116	0	0
Herbs	*E. Coli* O157:H7	1	108	8	0
Leafy Greens	*E. Coli* O157:H7	2	16	1	0
Onions	Hepatitis A	1	919	128	3
Nuts	*Salmonella*	1	42	10	1
Melons	*Salmonella*	4	156	30	2
Peppers	*Salmonella*	1	1535	308	2
Tomatoes	*Salmonella*	5	570	68	0
Melons	Shigella sonnei	1	56	3	0
TOTAL		**22**	**4,293**	**559**	**8**

Those are completely incompatible numbers. Even adding in fresh-cut in Table 14.

Table 14. FDA Outbreak Data for Illnesses Attributed to Fresh Cut, 2003-2008 **Commodity**	**Agent**	**Outbreaks**	**Cases**	**Hospitalizations**	**Deaths**
Leafy Greens	*E. Coli* O157:H7	10	599	223	6
Melons	*Salmonella*	2	99	22	0
Tomatoes	*Salmonella*	5	747	153	0
TOTAL		**17**	**1,445**	**398**	**6**

(see page 59 draft QAR for lined up summation numbers in the bottom row or mentally shift one box to the right)

What is going on? One possibility is they did a calculation based on the guestimates of nearly 50 million unreported and reported illnesses of food-born per year (most of which are unreported), then used the % of this total that is due to all produce illnesses, which are nearly universally non-farm, and then used the FDA outbreak data as if it identified farm-caused illnesses -- which it doesn't -- to calculate the % of this massive estimated

annual total due to FDA identified and FDA unidentified outbreaks or individual illnesses (It takes only 2 persons to make an outbreak; the assumption that non-reporting for say norovirus is the same as non-reporting for O157:H7 lacks credibility).

In other words they make a statistically impossible conclusion that ignores the fact that the general estimates of unreported illnesses are for all illnesses, while the pathogens of concern for produce are quite serious illnesses with mandatory reporting requirements by Federal and State health agencies, and the FDA and CDC are unlikely to miss such massive numbers, particularly when the overwhelming amount of produce in this country is centrally produced by the largest growers, and centrally handled or processed. Detectable outbreaks (2 or more illnesses) are highly favored.

The other possibility is they simply added the phrase "where the contamination occurred on farm" to the CDC epidemiological data of all illnesses, or the FDA fillet of that data that supposedly removes retail and at-home contamination.

A key indicator for me was their inclusion of norovirus (as in the cruise incidents) both in their text discussions of pathogens associated with produce and in their tables.Of course "fresh-cut" is actually "retail from the processor" if home consumed or eaten at a food-service or restaurant. This makes a retail or home the possible location of a processor caused outbreak.

In general, one has to read the QAR or the Analysis of Economic Impacts with the care of a lawyer, because when the context may an be on-farm discussion, the evidence then given is from processing, for example employee / sanitation caused outbreaks, leaving the impression of a record on-farm employee contamination causing outbreaks, when the record simply does not exist.

It may not technically be lying but it is deception in presentation without much of a difference in its effect.

[End of Appendix B]

APPENDIX C (Section II: Pesticides, heavy metals and radiological materials)

Let me give three examples just from Yolo County where I live, in lieu of a literature review:

Pesticides: The Frontier Fertilizer Superfund site was originally detected by a resident walking his dog next to a 500 acre farm property. His dog lapped water from a puddle, went into convulsions and died. As the ranch was incorporated into the city of Davis, deed restrictions were ordered for homes bordering the boundaries of the site, forbidding them from growing any plant that could be used for human food. The underground plume is migrating towards a corner of the ranch which may be used for small (urban) farms.

Heavy Metals: The Woodland Biomass power plant was designed to handle agricultural pruning, straw and other non-polluted plant and wood sources, so the ash could be used as mineral fertilizer for crops. During one shift, however, older painted material was routinely allowed in for some years. The subsequent lead contamination of nut trees was sufficient for an entire Deseret Farms orchard (walnuts or almonds) to be ordered out of food production.

Radiological Materials: An important Cold War era study at UC Davis looked at low level exposure of generations of dogs to radioactive compounds mimicking post-nuclear power accidents or post war long-term exposures. The PI described this to the San Diego biomedical community in 1971 as “the world’s longest running beagle poisoning experiment.” Generations of beagles thrived under these conditions without exhibiting increased cancer or even mutation rates. But the beagles did as all dogs would, and this had not been sufficiently planned for. It was discovered nearly thirty years later. Radioactive urine and feces contamination was sufficient to force a land swap with a neighboring farm.

These are not isolated cases. Complex industrial sludge had to be dredged from Oakland Harbor. Because it was too toxic to bring out to the Pacific ocean, the proposal was to use it to create artificial estuaries, in Susuin Bay, in neighboring Solano County or to use on agricultural lands. Similarly, before Anheuser-Busch located its plant in Fairfield, the extent of leaching from gold and silver mining ponds in the coastal range that border both counties, had to be studied. Cold war radiological testing occurred all over the country, including a site in Massachusetts close to where one of the Boston Marathon bombers was captured. This was contaminated in the course of materials testing of uniforms, which was discovered after the site was turned over to a local town considering it for parks and urban gardening.

It seems to me that the FDA has missed the increased importance of urban agriculture and urban farming across the country as a substantive new area to consider for at least

a linked Guidance under the Produce Rule. Some programs take urban pollutants into account, such as an urban farming program in Milwaukee where soil and compost is prepared on farmlands and brought into the city for urban use. Others may not. One also has to consider how plants take up and accumulate heavy metals and pesticides. This extends to root behavior: a famous case of Temik contaminated watermelon, began when a greenhouse previously used for flower production was used for growing watermelons, directly in soil mix bags to protect them from contaminants in the soil. The watermelon roots penetrated the bags.

The FDA also failed to consider not just the contamination of urban properties used for growing produce, but also the massive contamination of agricultural lands in other countries which may ship produce here under the same or equivalent Produce Rule.

The July 27, 2013 Wall Street Journal has an article on massive pollution of agricultural production in China from mining and industrial production:

“China's Bad Earth. Industrialization has turned much of the Chinese countryside into an environmental disaster zone, threatening not only the food supply but the legitimacy of the regime itself....Estimates from state-affiliated researchers say that anywhere between 8% and 20% of China's arable land, some 25 to 60 million acres, may now be contaminated with heavy metals.”

The Fukushima nuclear power accident introduced radioactive materials throughout the food chain, including in the ocean.

China and Japan are not the only countries in the world with these problems. Imported produce could come from any of them.

APPENDIX D (End of Section II: the nexus with deliberate acts of contamination)

In general, protections against deliberate acts are greatly enhanced by robust routine protections. Routine monitoring of watersheds, surface waters, and groundwaters could be said to be in the national interest and not just a problem for individual farms. For water issues, this is mentioned in the final section of the Comment under the concept of "smart" waters, watersheds, rivers, irrigation canals, aquifers and so on. The same types of monitors and instrumentation that are used for computer control of irrigation and drainage districts could be used with different detectors for real time monitoring of pathogens and other pollutants before water is delivered to, or used by, farms.

In our state, at least, any lands that may have run-off into the state's waters -- even if from rainfall -- are mandated to have reporting systems on runoff water quality. The California Farm Bureau and others managed to create districts for compliance so that individual growers did not each have to pay for their own monitoring. On a larger scale California has the California Integrated Water Quality Systems Project.
It strikes me that pathogen management in waters could be tracked in a similar way, with a slight twist. That is, it should be a governmental responsibility to provide useable irrigation water to growers and to report to them, in a timely manner, when water quality is compromised in a water system -- whether a watershed, a river, a canal or an area of an aquifer.

From comments it seems like even turbidity warnings would help.

Farms that wish to participate in a monitoring and information system by having instrumentation on or near their farms could do so. But they would be paid to cover their costs, for contributing to the water safety information system. The nexus with deliberate acts of sabotage, if this is covered in the Produce Rule, would allow funds to farmers for such equipment and maintenance to also come from DHS as well as other agencies.

Note that farmers would be paid and voluntary participants. Governmental agencies such as EPA and water quality districts etc. would finally be doing their job providing information to farmers, instead of getting farmers to pay to give them information. Ideally governmental agencies would take the responsibility for cleaning up waterways of the United States sufficiently to deliver useable safe water for irrigation to the farm

[End of Appendix D]

APPENDIX E (Section IV, Salinas, the FDA loses patience after the spinach crisis.)

A sanitized history of FDA produce industry relations is given in the supporting documents to the proposed Rule.

The CA LGMA was a direct response to the O157:H7 spinach outbreak in 2006 Pressure on the industry came from many directions.

As the outbreak was wrapping up, the FDA sent an unusual notice to the lettuce and industry in which the term “leafy greens” was used for the first time in a regulatory context. It includes the following section:

Next Steps
There has been a long history of E. coli O157:H7 outbreaks involving leafy greens from the central California region. Spinach processed by other manufacturers has not been implicated in this outbreak, but based on discussions with industry, and given the past E. coli O157:H7 outbreaks, FDA and the State of California still expect the industry to develop a comprehensive plan which is designed to minimize the risk of another outbreak due to E. coli O157:H7 in spinach grown in central California. While this plan is under development, FDA and the State of California reiterate previous concerns and advise firms to review their current operations in light of the agency's guidance for minimizing microbial food safety hazards.

FDA and the State of California have previously expressed serious concern with the continuing outbreaks of foodborne illness associated with the consumption of fresh and fresh-cut lettuce and other leafy greens. After discussions with industry, FDA and the State of California, as part of a longer term strategy, now expect industry to develop a plan to minimize the risk of another outbreak due to E. coli O157:H7 in all leafy greens, including lettuce.

Implementation of these plans will be voluntary, but FDA and the State of California are not excluding the possibility of regulatory requirements in the future. FDA will be holding a public meeting to address the larger issue of food borne illness linked to leafy greens later in the year once the current investigation is complete.

FDA Statement on Foodborne E. coli O157:H7 Outbreak in Spinach. This statement is current as of October 6, 2006 (FDA website).

[End Appendix E]

APPENDIX F (Section V, WF Brinton on human pathogens in composts)

In California, at least composting is also regulated by air pollution/quality districts for volatile organic compound (VOC) emissions. One typical definition is "GREENWASTE COMPOSTING means composting of greenwaste by itself or a mixture with foodwaste, or with up to 20 percent manure, per pile volume basis."

William Brinton's survey of fecal indicators in West coast composts still seems to be the best published source, and his findings from five years ago are quite disturbing on this point [WF Brinton, P. Storms and TC Blewett, Occurrence and Levels of Fecal Indicators and Pathogenic Bacteria in Market-Ready Recycled Organic Matter Composts Journal of Food Protection, Vol. 72, No. 2, 2009, Pages 332–339; also reviewed in Food Safety News, May 22, 2010].

Brinton tested for salmonella, O157:H7, Listeria spp, (pathogenic) Listeria monocytogenes, Clostridium perfringens, fecal streptococci, E. coli, and fecal coliforms; the latter being the indicator used in standards to meet EPA's 503 rule for composting sewage sludge, which is now used for many kinds of recyled organic matter ("ROM") composting. They compared results between states (WA, OR, CA), composting methods, source materials, physical/chemical properties, volume produced annually, and other factors including by the California Maturity Index for finished compost.

"We detected measurable E. coli O157:H7 in samples from three facilities. These facilities were in the large facility group and were situated within important vegetable growing regions. One of these three facilities also produced compost with one of the highest counts of C. perfringens (8 x10[to the 4th] CFU/g). This obligate anaerobe is indicative of very wet, fecally contaminated conditions. We retained the sample with the highest E. coli O157 count for 3 weeks at 5 [degrees] C, and it was still positive when retested. To confirm these results, we sampled compost from the same site 3 months later, taking the sample from a different batch of compost; the new sample was again positive for E. coli O157. To investigate whether pathogen characteristics persist over time at a facility, five facilities that produced composts with elevated fecal coliform counts were resampled in two regions within California (21 to 146 days after the first sampling). At three of the five facilities, these second samples also exceeded the fecal coliform limit."

This was two years after the 2006 spinach outbreak, in California "important vegetable growing regions."

[End Appendix F]

APPENDIX G: Long-term illness; foreign farm exemptions; Federal Pre-emption.

These three topics are not covered elsewhere in the Comment.

Long term vs acute illness and death. FSMA calls for produce production that protect against serious health impacts including death. it seems to me that the proposed Rule used the wrong standard for serious health impacts. It appears to only consider acute illness as a serious health impact, even when the symptoms and consequences are considered “mild” as in norovirus infection. Nothing in FSMA supports this standard, and long term or chronic conditions subsequent and to a degree saparte from the immediate illness also need to be considered. (The Economic Analysis of Impact attempts this for the specific diseases, but not their associated conditions).

It appears that the intent of Congress in passing the Tester amendment on farm size and local production within the United States has been extended by the proposed Rule to cover foreign countries producing for import, so long as they are within the milage categories of the borders of the United States or its territories or the Commonwealth of Puerto Rico. This does not seem to have been the intent of Congress.

The status of FSMA as a federal pre-emption of State laws does not seem to have been discussed and should be: this directly affects California, Arizona and Florida for example.

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COMMENT COVER LETTER

The comment begins with “The proposed rule is a mess...” and ends with “The Secretary would be a fool to sign it.” In between I criticize the justifications given for the proposed rule, its structure and some key parts of its content.

A central concept behind the critique is that the rules developed for leafy greens in California, and for other commodities with a persistent record of outbreaks, appear to be the models for this proposed rule. Ripped out of their original contexts, they are not appropriate for a national rule for all produce. However, the analysis given for the proposed rule appears to have been distorted to achieve this result.

“Only a fool would grow fresh produce without considering food safety” especially when it is going to be eaten as a raw fresh vegetable without a kill step. The question is the balance, what is reasonable, and what is actually known. To some extent it also involves what the FDA is capable of doing well. Separating out fresh-cut and sprouts, I give some alternatives to the proposed rule, one from a fresh-cut processor that takes four sentences, and one based on my own conclusions. These could be considered different approaches to take in a revised rule. .

Although I interviewed a number of people to get some perspective of my own, both for attribution and for background, none of them are responsible for the use I make of their information or any other judgements or assertions in this Comment. Their approved interview notes or statements, are part of the Comment. In Jim Prevor’s case I use part of a recent column with his approval. I would have liked to include more people who disagreed with me.

Much of the original work that informs this comment was done in 2008 and resulted in the CAFF Guide to food safety issues and their politics. The basic idea in the Guide was that a new type of pathogen O157:H7 affected a new type of processing without a kill step, fresh-cut. At the time fresh-cut was not even recognized as processing.

The CAFF Guide and my 2010 written comments to the proposed Preventative Controls for Fresh Produce, Request for Comment are incorporated by reference and attached as separate pdf’s.

I was encouraged to do a 20,000 foot overview of the proposed Rule, how it fits together and with other rules and laws. It does not look good from 20,000 feet and it looks worse up close.

Dan Cohen; August 02, 2013

3 Attached pdfs: Cohen Comment, CAFF Guide, 2010 FDA Comment