

Comments of the Community Alliance with Family Farmers on docket # FDA-2010-N-0085 relating to forthcoming FDA guidance on food safety preventive controls for fresh produce

Contact:

David Runsten
Director of Policy and Programs
Community Alliance with Family Farmers (CAFF)
PO Box 363
Davis, California 95617
530-756-8518 ext. 25
530-756-7857 fax
www.caff.org

The Community Alliance with Family Farmers (CAFF) appreciates the opportunity the Food and Drug Administration is providing for comment prior to setting standards for fresh produce at the farm and packing house level.

CAFF is a 30-year-old non-profit organization that fosters the culture and agriculture of small to mid-sized family farms in California. Our work spans the entire food production and distribution chain. Our Biologically Integrated Agriculture program just received an Integrated Pest Management Innovator Award from the California Department of Pesticide Regulation. This program works directly with farmers to produce environmentally sustaining and nutritious food. Other CAFF programs expand markets for family farmers and shape local distribution channels to better serve food service institutions and school cafeterias. Our Buy Fresh Buy Local guides put consumers directly in touch with fresh farm produce, farmers markets and Community Supported Agriculture.

In formulating our specific comments CAFF relies on the following broad principles:

- Food Safety regulations should be focused on the highest risk activities.
- Food Safety requirements must be based on science directed toward the goal of achieving the objective of safer food, rather than simply addressing every possible risk no matter how remote.
- The natural environment can and should be enhanced in conjunction with managing for food safety.
- Private proprietary and state level food safety metrics must be superseded by federal regulation.
- All farmers want to produce safe food. Education and training through a variety of agencies and NGO's will ensure compliance.
- Enforcement of food safety standards should be handled through local agencies and NGO's.

It is ironic that produce safety regulation is being designed for the benefit of the agricultural sector that has caused the most outbreaks, and imposed on the vast majority of farmers who have not caused outbreaks. The very design of commodity-specific regulation is not for farmers or consumers or even because of the different biology of each fruit and vegetable, but to allow processors and handlers to deal with the farm production of each crop as a commodity, which they can then process, mix and combine in pre-cut packaging in any combination that they think will sell. If it were just a matter of biology, "leafy greens" would not be treated as a "crop".

The uses of commodity specific guidelines for farm safety under the current and proposed regulatory frameworks are poorly conceived with potentially disastrous consequences. These include: environmental

degradation; massive loss of farming operations, including suppressing beginning farmers; the inhibition or destruction of local production and organic production; the inhibition of development of new agricultural methods and market opportunities; and, finally, the imposition of conflicting and incompatible food safety and environmental regulations on surviving farms, with exponentially growing complexity.

We believe that the FDA should focus on high-risk practices and regions and leave the vast majority of farm operations alone. Over time, all farmers can be educated about activities that might create food safety risks and can implement risk-reducing measures on their farms. In the following comments we first discuss our recommended approach to food safety in produce and then provide some answers to FDA's questions for this docket.

Supported FDA and HHS actions

1. FDA should separate its regulation of the so-called "fresh cut" or pre-cut produce industry from broader traditional produce farming. Treat it as a vertically integrated industry and adopt "farm to fork" food safety regulation of the sort supported by this industry.

- Require a special registration and licensing for any processor delivering pre-cut produce in the United States, whether foreign or domestic.
- Require a special registration and licensing for any farm operation delivering to pre-cut processors selling into or operating in the United States.
- Require that registered and licensed pre-cut processors only buy from registered and licensed farm operations.
 - We recognize that this is inconvenient for the pre-cut processing industry, which desires maximum flexibility in acquiring produce on spot markets at the lowest possible cost. However, given the higher risks associated with pre-cut, we believe that the processing industry should assume responsibility for additional food safety costs associated with this type of production rather than asking the FDA to require all farmers to adopt unnecessarily stringent food safety metrics.
- Establish specialized standards for farmers producing for pre-cut processing -- a largely industrial, national, and higher risk market – distinct from approaches to food safety for other farmers. Of course even standards for the pre-cut market must be compatible with environmental protection laws and with organic standards for organic farmers. Although the Leafy Green Marketing Agreement standards have not been entirely effective in preventing pathogenic contamination of pre-cut leafy greens, they are nevertheless an attempt at designing metrics appropriate to this vertically integrated system.
 - We recognize that this may be inconvenient for farming operations that grow for both the fresh and processing markets. However, there would be nothing stopping them from applying the more stringent processing metrics to all of their production, though this might put them at a slight cost disadvantage in the fresh market. It is greatly preferable to requiring all other farmers growing only for the fresh market to adopt unnecessary food safety metrics.
- Put the inspection of pre-cut processing plants into the category for highest frequency of inspection, including review and certification of their plans to meet food safety standards and to document the implementation of these plans. If necessary, institute permanent on-going inspection. Since the USDA's record on meat inspection with permanent ongoing inspection is

not encouraging, analyze why this is and improve on their systems of facility control for inspecting pre-cut produce processors.

- Develop mandatory food safety objectives and standards for pre-cut processors from receipt of product through delivery, including maintenance and recording of the cold chain. Processors could be allowed to meet those standards by their own methodologies until such time as there is clear scientific evidence of which methods work best, whether for test and hold, composition of wash water, etc.

2. Regulate Use-by Dates for food safety and consumer protection—rather than for simple shelf life or “spoilage”—and require them for all pre-cut produce. Include consideration of actual expected consumer behavior with respect to use-by dates.

- We note that in the 2006 spinach outbreak most of the sickened consumers were eating the product close to or beyond the use-by dates.

3. Research and regulate commodity-specific packaging for produce, so that growers who are packaging on-farm and processors have access to safe, tested, containers for both pre-cut and whole produce.

- Farmers of all sizes should be able to buy approved packaging materials that are designed and tested NOT to increase pathogen growth. We recall the example of mushrooms, where boxes that were not properly aerated were causing food safety problems, as well as the experience with tight plastic webbing on iceberg lettuce heads that dramatically increased salmonella incidents, possibly due to the plastic cutting the leaf tissue and providing entry and growth points for pathogens.
- HHS needs to deal with the broader issue of food safety in packaging as well, such as chemical release from liners or packages in processed products.

4. Work with the retail buyers, restaurant chains, and others concerned about food safety liability to develop uniform food safety standards commensurate with the risk presented by different crops, regions, and degree of processing. The intent should be to establish standards that protect all participants from liability related to questions of best management practices and to eliminate the use of “super metrics” by private buyers. Food safety should not be a basis for competitive advantage in the produce industry. The current efforts of United Fresh Produce Association to create a harmonized set of food safety metrics may be the basis for large-scale, commercial standards.

The FDA farm safety standards should supersede all other metrics and GAPs including industry specific programs. Currently some farms find themselves attempting to comply with as many as a dozen different sets of metrics. Such a situation leads to resistance and less compliance overall. FDA must find a way to control environmentally destructive and unscientific “super metrics.”

5. Cooperate with the Department of Justice and the EPA in prosecuting those companies that have used their economic power and have colluded to force farmers to violate environmental protections and laws under the guise of food safety requirements (super-metrics).

6. Improve food safety outbreak investigations

- Develop a comprehensive three-part approach to outbreak investigations, including the CDC, FDA and other agencies.

(1) The current CDC role: stopping the outbreak ("putting out the fire").

(2) An expanded FDA-CDC-state investigation of causation simultaneous with the trace-back. This would be equivalent to a fire marshal's or arson investigator's role.

(3) Lessons learned. A systematic analysis of the outbreak case that indicates where systems failed—or never existed—and improvements that could be made (in processing, documenting, or more rapid or complete investigative tools), and compares this case to previous cases so that there is a systematic build-up of knowledge, analysis, prevention, and investigative tools over time.

- Currently most or all of the weight is on identifying the source and stopping the outbreak—by analogy, putting out the fire. Since there appear to be many more systemic issues involved with produce outbreaks, much greater weight needs to be given to causal investigation, why the outbreak occurred, and lessons learned in order to prevent future outbreaks. The CDC seems to go from outbreak to outbreak—from fire to fire—without a priority to determine causes and preventative measures. There needs to be much greater emphasis on causation, a fire marshal's role or an arson investigator's role; and lessons learned that can lead to prevention, the equivalent of new building and materials codes, sprinkler requirements and so on. Although techniques of rapid response to a crisis have evolved significantly, comprehensive investigation has not. It's not even clear whose job it is to carry out all parts of a comprehensive investigation for each outbreak.
- Modify the CFSAN and other investigators' manuals to reflect the three parts of a comprehensive investigation, which in any case shade into each other, and develop adequate human and technical resources to carry out a comprehensive investigation for each produce outbreak.

In particular, it should be standard practice to interview all employees, not just management, with adequate translation capabilities and worker protections to allow them to speak freely. These were not even included in the last CFSAN investigators' manuals that we reviewed.

- Give at least equal weight to the investigation of processing plant operations in pre-cut produce outbreaks, along with farm operations, as possible sources of contamination, and develop the investigative methods to carry out this quite difficult task. You cannot find what might be there if you have not looked for it or do not have the tools to find it.

7. The USDA and HHS working group on food safety needs to develop into a permanent institutional part of government. Its primary role should be to coordinate research, information, responses to, and control measures for, human pathogens and their evolution in the environment: including the farm environment, animal production, the industrial and commercial environment and the medical (healthcare) system.

Asking produce growers to control pathogens while increasingly dangerous pathogens are being inoculated into their farm environment seems futile. The produce growers are not, for the most part, putting these pathogens into the farm environment, as they are down-wind, down-stream of the sources. We need to cut the flow of human pathogens into the agricultural environment and prevent the evolution (selection) of

more dangerous and less treatable pathogens, whether from animal agriculture, industrial processes, commercial products, or medically-caused etiologies.

8. The Waters of the United States, and the Waters of the respective States need to be evaluated for human pathogen content by the federal and state governments, and this information should be made available to farmers and processors in a timely and on-going manner. This is a public health matter and should not be the responsibility of farmers.

9. CAFF believes that we need a new type of researcher and better information to base decisions on, as well as additional resources for research. The Land Grant Acts need to be modified so that HHS can play an increasingly important role, roughly equivalent to the USDA. In particular, we recommend that HHS fund new professional Extension Specialist positions (MD, PhD, DVM epidemiologists) on human pathogens in the environment, starting with those state university systems that have Veterinary Medicine Extension and DVM programs as well as medical schools. These positions had, at one time, strong support within the FDA, and may still.

10. HHS needs to make it a priority to fund research on reducing the medical harm caused by human pathogens on produce and meat. When prevention fails, the consequences of contamination by STEC *E. coli*, Listeria, salmonella, and other pathogens need to be mitigated by effective, rapid, primary-physician-based tests and effective therapeutics. In particular, there needs to be much more effective treatment for hemolytic uremic syndrome (HUS) caused by STEC *E. coli*. Telling a child to eat her spinach, or drink his juice, or finish her hamburger should not be a medically crippling act or a death sentence.

Responses to FDA Questions

Comments to inform the development of (1) Safety standards for fresh produce at the farm and packing house and (2) strategies and cooperative efforts to ensure compliance:

1) Role of the good agricultural practice guidelines entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (GAPs Guide, Ref. 6)

CAFF finds the above-mentioned “Guide” to be serviceable and preferable to many of the metrics and GAPs-type documents currently available for use in developing an on-farm food safety program. However the document is inadequate in addressing the concerns and efforts of many farmers to preserve and protect the natural environment while simultaneously incorporating food safety practices on their farm, something that has come to be known as co-management (of food safety and the environment). Farms certified as Organic under the National Organic Program (NOP) are in fact required to maintain or improve the natural resources of the farm including soil, water, wetlands, woodlands and wildlife, and many private GAPs make this impossible.

The FDA should confine the proposed safety standards to broad areas of concern, leaving the specifics of farm GAPs to the operator. By example we find the specific “metrics” of the CA Leafy Green Marketing Agreement (LGMA) to be suitable for use by only the largest producers selling primarily into the processing market. LGMA metrics such as water testing before each harvest are designed for the farmer harvesting large blocks of produce all within a matter of days. This metric would not work for a family farm that harvests one field multiple times a week throughout the season. In addition we find little science-

based benefit from such practices, particularly the LGMA water *E. coli* thresholds that seem to have been based on swimming pool standards.

CAFF would like to call your attention to a set of GAPs we developed with the direct input of organic and diversified farmers as well as Cooperative Extension in California (see attached). They are considered appropriate for diversified fruit and vegetable farms selling perhaps \$500,000-\$5 million of produce annually. These GAPs also detail the relative risk of animals (both wild and domestic) common to the farm environment and those in most danger of having their habitat destroyed mostly without any scientific basis, in pursuit of food safety.

2) Standards for domestic and foreign growers and packers

As a simple matter of fairness, and because fresh produce arrives daily from foreign sources, all imported produce food safety standards must be in harmony with the same standards as domestic produce. Imported and domestic produce should be brought under food safety standards simultaneously so as to avoid a cost of compliance advantage for either source.

It is well known that in many developing countries surface water sources are much more polluted than in the United States (including the use of untreated sewage water in some areas—e.g. the case of the Valle de Mezquital north of Mexico City, which had a long history of using *aguas negras* on vegetables, a practice that the Mexican government halted during the NAFTA debate only to see it re-start once NAFTA was passed), standards of worker hygiene are lower, chemicals that are banned in the United States are permitted for domestic production, and farmers with little or no formal education are feeding product into aggregators. Even though such conditions are not characteristic of commercial export regions, nevertheless the notion that such produce cannot find its way into export channels is just hubris. These realities are of course very uneven across the landscape, but we believe that many of these “low-cost” regions of production present much higher risks than do family farmers producing for local markets in the United States. We strongly urge the FDA to focus attention and resources on imported produce, particularly produce brought in by brokers who may not be involved in its production. We are not opposed to the importation of produce, but we believe it should be possible for the FDA to identify and monitor foreign regions that present particular food safety risks.

3) Identification and prioritization of risk factors

The FDA should enact and enforce farm food safety measures by tackling the highest risk produce and processes first. CAFF finds the record keeping of produce outbreaks inadequate for the proper assignment of risk. Outbreaks should be tracked as to whether or not the produce responsible was in any way processed. Any analysis of produce outbreaks is hampered by this lack of careful recordkeeping. However, well-publicized outbreaks of contamination have shown that processing produce adds to the risk of contamination. Produce destined for processing—unless the processing has a clear kill step—should be assigned the highest risk factor, particularly produce destined for fresh-cut processing and bagging.

Our review of outbreaks associated with leafy green vegetables—which we submitted to the USDA’s National Leafy Green Marketing Agreement hearings—concluded that virtually all of them were associated with fresh-cut, bagged products. Even though the FDA has focused on leafy greens, melons, and tomatoes as high-risk crops, it has not distinguished between production for the standard whole-produce market and production for fresh-cut processing. Therefore it has assumed that production for

either market is equally risky, when there is no evidence that this is the case. While this approach may be convenient for large operations that produce for both market segments, it is unfair to farmers who produce only for the whole-product market and particularly unfair to highly diversified farmers who produce dozens of crops and are not capable of adopting highly specialized metrics for three rows of produce. We do not believe that whole heads of lettuce or whole pole tomatoes are high-risk products and we believe that the FDA is mistaken in treating them as such.

The outbreak record seems to show particular geographic-pathogen hotspots for individual pathogens and crops. This should be studied further. These hotspots need individual attention, recognizing that sometimes changes in processing methods alone have reduced the incidence of outbreaks.

4) Environmental assessment of hazards and possible pathways of contamination

We believe the completely natural environment poses a minimal risk to producing safe food. Most all food safety issues can be traced to humans or human interventions, such as confined animal operations and the associated manure. An adequate set of safety standards/GAPs should recognize the difference between the low risks of the natural world and the higher risk that comes from the introduction of industrial processes. It follows then that animals are not a single block with the same risk profile across all species, and further, different methods of animal production increase or decrease risk. The FDA should consider that it is well documented that feeding cattle grain increases the incidence of pathogenic *E. coli* and feeding cattle hay or grass decreases the incidence. Also recent wildlife studies in California have found no deer that are carriers of human pathogenic bacteria. Given that cattle and deer are lumped together in many industry sponsored "metrics," it is clear there are a number of mistaken assumptions written into those metrics that threaten the environment. In general, wildlife and their habitat are a low food safety risk. Research shows that grasses and wetlands can significantly filter *E. coli* pathogens, and soils with diverse microorganisms are antagonistic to these pathogens, thereby increasing the safety of food. The FDA should make it a priority to research and assess these risks in detail. (The attached CAFF GAPs have an appendix devoted to wildlife studies).

5) The impact of scale of growing operations on the nature and degree of possible food safety hazards

Even very small farms cannot be considered immune from pathogen contamination. However there is a higher degree of supervision when the owner rather than hired help is overseeing the daily operations. The larger farms that supply most of our produce are dispersed over large distances, often in non-adjacent fields. Management and responsibility is dispersed among many firms and individuals, increasing the chances that a risky anomaly is missed. With proper information and training the small farmer will operate a very safe farm, if not the safest farm possible. The almost complete lack of outbreaks associated with small farm produce in the United States is indicative of this reality.

An example of the different risks presented by farm scale can be found in vegetable harvesting methods. Whereas very large farms regularly use mechanized equipment, such as actual mechanical mowers for baby lettuces or harvesting belts for other vegetables, small farms generally harvest vegetables entirely by hand. The scale and pace of the harvest allow for the farmer and his workers to examine each plant individually, increasing their ability to detect animal feces or other contamination. On a small farm, it is not necessary to exclude an entire field or a large part of a field from harvesting due to animal intrusion, because each plant will be examined before it is harvested.

In any case, the mixing of large quantities of produce in fresh-cut processing operations and its subsequent distribution across the country presents a higher likelihood of widespread illness outbreaks than do small-scale local sales.

6) Methods to tailor preventive controls to particular hazards and conditions affecting an operation

Commodity specific safety standards are inappropriate for a diversified family farm. Good in-depth training in food safety principles will enable farmers to identify and control for particular hazards and conditions. There will never be an analytical tool that can replace the well-trained observant farm operator motivated by concern for the well-being of the end consumer. However it might be helpful for the FDA to develop a decision tree type of tool that, combined with training, can help point to specific hazards during an initial farm assessment.

We find the application of a HACCP analysis, subsequent deployment of associated committees and resources, and production of paperwork to be counter-productive in the ever changing environment and workload of a family farm.

7) Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations

Preventative controls should be flexible and focus on general principles, training and processes first. The most effective preventative controls are the simplest. Deployment of technology in pursuit of food safety on the farm will tax the family farm resources to the limit.

Given the long lead time it takes to change a Guidance document and the fast pace of food safety research, it would be a mistake to “cast in stone” any but the most commonsense preventive controls, e.g. hand washing before work and after using the toilet

8) Coordination of produce food safety practices and sustainable and/or organic production methods

To coordinate sustainable and organic practices with food safety the FDA should establish a permanent advisory group consisting of the National Organic Standards Board and NGOs working in this area, such as Salmon Safe, Food Alliance, and the various sustainability efforts (e.g. Stewardship Index for Specialty Crops).

9) Coordination of produce food safety practices and environmental and/or conservation goals or practices

To coordinate environmental and conservation goals with food safety practices the FDA should establish a permanent advisory group consisting of the Natural Resources Conservation Service, EPA, and NGOs working in this area.

11) Microbial testing

Microbial testing should not be a requirement of on-farm food safety standards established by the FDA. Even the largest producers and most sophisticated regulators poorly understand microbial testing and its

uses. We do appreciate that microbial testing can assist in assessing the effectiveness of controls, but the training required to properly administer such verification testing would be beyond the resources of most farm operators. In addition testing costs vary widely and can run as much as 500% higher for the infrequent user.

To illustrate the principles above: a careful mapping of the farm water system would reveal risk factors, and control of those factors would accomplish more in pursuit of food safety than using testing as a control measure.

If the FDA believes that microbial testing is an appropriate control measure then the FDA should provide training in detailed and specific sampling and testing procedures.

12) Post-harvest operations and the role of the current good manufacturing practices in 21 CFR part 110

The produce safety standards being contemplated must be very clear as to what constitutes produce processing and what is produce prep for market acceptance. We have noted the role that pre cut and processing play in increasing produce contamination risk. However we find simple prep procedures for market acceptance to pose almost no risk of exacerbating a contamination incident. Simple farm or field prep of produce can be incorporated into the hygienic practices of a simple set of GAPs. Therefore we believe that part 110 should be reserved for situations where actual processing is practiced. Pre-cutting vegetables and packaging salads is considered processing.

13) Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce

The production of records and other documents is not central to ensuring safe food practices. Records and documents should be required only for primary assessment or activities that might be one-time or annual in nature, such as employee training, water assessments, and surveys of surrounding land activities. Requiring records concerning daily activities will be counter-productive and lead to involuntary non-compliance. Traceability records should be limited to verifying “one up, one down”. And since NOP certification already ensures adequate traceability, certified organic product should require no additional documentation of traceability.

14) Strategies to enhance compliance

The FDA should devote considerable resources to ongoing and permanent training programs. It could be useful to develop a decision tree type of matrix for use by the grower in developing a food safety plan and also serve as a training aid. The FDA should also specifically train its employees in the challenges of the co-management of food safety and conservation. The FDA should license other more local agencies and NGOs to do trainings and inspections. The FDA should focus on working with the existing farm culture in America and other countries in achieving its goals.

For most farm operations the approach should be informational and not regulatory. It's possible that this approach could lead to requiring produce farmers to have one trained food safety employee or manager, as is the case for restaurants in many states, as validated information on food safety issues becomes preponderant, specific and available. And just as in California the required “pest control advisor” is often the farmer, so could the farmer be his own food safety specialist.