Daniel B. Cohen
Maccabee Seed Company
2315 Shenandoah Place, Davis CA 95616
(530) 753-4974 Fax (530) 756-7094

In re: docket number FDA-2010-N-0085

Preventive Controls for Fresh Produce, Request for Comment
Federal Register Vol. 75, No. 35, Tuesday, Feb. 23, 2010/Notices
Page 8086 et seq.

To:

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

This comment is my sole opinion and best judgement on the status of FDA regulation of food safety on farm. Others are free to use elements of this as they find appropriate. Quotations are from memory, but I think they are accurate. Background documentation can be found in the "CAFF Guide to Proposed Food Safety Regulation" January, 2008, which is part of the Docket record. The continued environmental destruction over the last two years has been well documented by others. If I could only make one single recommendation from this analysis it would be the following:

** Use-by dates on packaged pre-cut produce should be regulated by the FDA for consumer safety*.

My view is that this elementary step, well within the FDA's competence and authority, would have a broader impact on improving produce safety than the entire package of proposed on-farm regulations contemplated in the Docket. It is not the only recommended action.

Preface

"*What you call a spinach harvester, I call a pathogen inoculator*."

--- FDA Hearing Officer, Public Hearing on the Safety of Fresh Produce, Ronald V. Dellums Federal Building, Oakland California; March 20, 2007.

If the road to hell is paved with good intentions, it also can be paved with bad intentions. My judgement is that the uses of commodity specific guidelines for farm safety under the current and proposed regulatory frameworks are poorly conceived with terrible consequences. These include: environmental degradation, massive loss of farming opera-

tions, 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.

If the good intentions are the enhancement of safety and security of an affordable fresh produce market for consumers, particularly the reduction of human pathogen transmission, what are the bad intentions? I see the main conflict with simply enhancing food safety coming from the desire by processors of fresh produce, the pre-cut or fresh-cut industry -- and in the past the juice industry, to reduce liability by shifting as much attention as possible from their own methods and standards to farmers and the farm environment. My impression is that federal and state agencies have been complicit with this strategy for many years.

"*We were so close*!"

--- Chief science officer of one of the largest fresh produce associations, complaining that the ranch identified as the possible source of the 2006 O157:H7 spinach outbreak and recall was only organic in transition and not already organic. Heidrick Ag History Center Woodland California; organizing meeting for the California Leafy Green Handler Marketing Agreement (LGMA) and Board, February 23, 2007.

My observation and conclusion is that motivations go beyond the deflection of processor liability into three other areas: (a) through handling agreements or federal regulations, processors can add to their considerable economic domination of the industry, a near oligopoly, by controlling the state and federal powers of a food safety response (every crisis is an opportunity), (b) there is a lingering cultural war going on in which a 1950's model of a sterile farmscape controlled by chemicals is preferred to any alternative -- even when this model is against their own growers' economic interests and their own processor-members' organic markets, and (c) there is a desire -- or no objection-- to eliminate any competition, including in particular local food production, which is perceived as an economic threat.

The consequences I describe as terrible, from an industrial perspective are beneficial -- if they lead to reduced competition and greater control. That this approach in the end is self-destructive, not even rising to un-enlightened self-interest, is beyond the scope of my comments. but I think it is fair to describe these intentions, as well as the deflection of liability, as "bad" intentions that have informed poor public policy on food safety.

It seems to me that the FDA should have its greatest capacities, capabilities and expertise to regulate the major sources of national food-borne pathogen produce outbreaks in the last 15 years or so, which come from the processing, packaging and shipping of pre-cut produce for both retail sales and food service. It clearly should be able to regulate these specialized processors, as it does other food processors. Whether it has the capability of regulating even the farmers who supply this market, much less other farmers, is an open question, but the FDA should make farming for the pre-cut market the

focus for any initial, perhaps experimental, attempts at farm regulation. Until the FDA demonstrates that it can do the job it has expertise in, is mandated to carry out, and has the highest probability of reducing outbreaks (regulating food processing, including pre-cut processors) it should act with restraint in areas where it has less expertise. I will start with actions the FDA and HHS could take that I think are appropriate and could be broadly supported. The rationale for some of these actions will then be explained.

The net effect should be to correct the imbalance of food safety regulation between farmers and the rest of the food production and distribution system.

Supported FDA and HHS actions.

(1) Regulation of Use-by Dates for food safety and consumer protection, including consideration of labeling and actual consumer behavior with respect to use-by dates.

(2) Commodity-specific regulation of 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. HHS needs to deal with the broader issue of food safety in packaging as well, such as chemical release from liners in canned products.

(3) By regulation or additional statutory authority, provide a safe-harbor exemption for contracts and from torts when produce is not delivered due to demonstrated food safety concerns.

(4) Develop and regulate fair market produce safety standards for at least major purchasers, such as Wal-Mart (sui generis in the marketplace) and other major buyers such as food service and major restaurant chains. The intent is to end, on the one hand, the use of supermetrics on farms and to end, on the other hand, forcing suppliers who have developed elements of good food safety, such as chain of identity, to compete with suppliers who have not, for the same pricing.

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

(6) Develop mandatory food safety objectives and standards for pre-cut processors from receipt of product through delivery, while allowing such processors to meet those standards by their own methodology until such time as there is a common body of evidence on which methods work best.

(7) At least annual inspection of each pre-cut processing plant, including review and certification of their plan to meet food safety standards, to implement and to document the implementation of these plans. If necessary, permanent on-going inspection. Since the USDA's record on meat inspection with permanent ongoing inspection is not encouraging: analyze why, and improve on their systems of facility control for inspecting pre-cut produce processors.

(8) Require specific registration, licensing and regulation for any processor delivering pre-cut produce in the United States, whether foreign or domestic.

(9) Require specific registration, licensing and regulation for any farm operation delivering to pre-cut processors selling into or operating in the United States.

(10) Require that registered and licensed processors only buy from registered and licensed farm operations.

(11) Separate out the regulation and standards for farmers producing for pre-cut processing -- a largely industrial, national, and higher risk market -- from all approaches to food safety for other farmers. Any standards, including for the pre-cut market, must be compatible with environmental protection laws, and with organic standards for organic farmers.

(12) Develop a comprehensive three part approach to outbreak investigations, including the CDC, FDA and other agencies: ending the outbreak, determining the cause, analysis and lessons learned.

Currently most or all of the of the weight is on identifying the source and stopping the outbreak -- by analogy putting out the fire. Since there appear to be much 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 further outbreaks.

The CDC's responsibilities take it from outbreak to outbreak -- going from fire to fire -- without a priority to determine cause 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.

(13) 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 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 I reviewed.

(14) Give at least equal weight to the investigation of plant operations in pre-cut produce outbreaks, along with farm operations, as possible sources, and develop the investiga-

tory methods to carry out this quite difficult task. You cannot find what you have not looked for; or do not have the tools to find, if it is there.

(15) 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.

(16) The USDA and HHS working group on food safety needs to develop into a permanent institutional part of government. It's 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 environments at gulf oil-spill rates seems futile. We need to cut the flow of human pathogens into the farm and 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.

(17) 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 ongoing manner.

(18) Along with the pre-cut produce industry, which is higher risk, the outbreak record seems to show particular geographic-pathogen hotspots for individual pathogens and crops. These hotspots need individual attention, recognizing that sometimes changes in processing methods alone have reduced incidence of outbreaks.

(19) I believe we need a new type of researcher and better information to base decisions on, as well as additional resources. The Land Grant Acts need to be modified so that HHS can play an increasingly important role, roughly equivalent to the USDA.

In particular, I would 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.

(20) HHS needs to make a research priority 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, and 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 a hamburger should not be a medically crippling decision, or a death sentence.

Discussion

"*I'm asking you to put me out of business. There's a lot of other law I can practice*."

--- Food safety attorney Bill Marler, after defining strict liability for an audience largely made up of leafy green growers and processors, at a luncheon meeting at the National Steinbeck Center, February 28, 2007. Fresh spinach salads and cooked spinach dishes were served.

There have been two produce associated outbreaks under investigation when I started writing this comment, a precut packaged romaine lettuce outbreak of the STEC E. coli O145, associated with food service distribution, and a Salmonella newport outbreak in multiply-packaged alfalfa sprouts. Marler Clark appears to be filing lawsuits in both cases.

The Freshway Foods pre-cut romaine outbreak is the first reported outbreak in the U.S. associated with O145 STEC E. coli and appears to be the first associated with Arizona desert production. According to the CDC the romaine was produced on an unidentified Yuma farm and distributed by the Andrew Smith Co., grower shippers of Salinas CA, to Freshway Foods which is in Youngstown Ohio. Both Arizona and California have leafy green processor marketing agreements covering about 90% and 80% of all production (respectively). Andrew Smith Co. of Spreckles CA, a small hamlet in the Salinas Valley about 2 miles from Salinas, is on the CA LGMA membership list as of May 21, 2010. Cases presented as bloody diarrhea and three people have been hospitalized with HUS.

Could the 20 point checklist (above) have prevented or mitigated this outbreak if already implemented? The grower of pre-cut lettuce would have been registered and licensed and operating under special rules for production, as would the processor. If water was contaminated with pathogens, Arizona or the U.S., monitoring for all STEC E. coli, would have reported this to growers and additional safety procedures could have been implemented. Cattle operations some 20 miles away would have been monitored for human pathogens and steps taken to eliminate them, and to additionally stop their flow into the environment from these sources by potential vectoring routes of water, windblown dust, manure, waste products, and birds (also on people and vehicles). The processor investigation would be looking at all potential causes of contamination including human health at the plant, product cross contamination, failure to implement a sound and certified processing plan, failure of packaging materials and cold chain, and

interviewing workers as well as management. The (at least) annual inspections and certification might have prevented a contamination and outbreak. Almost all product was already out of the distribution chain at the time of recall; shorter or safer timelines for use-by dates might have reduced disease incidence. The hospitalized patients would have more effective HUS treatment that, hopefully, would prevent a lifetime of damage.

It looks like the alternatives presented could have been effective at preventing or limiting damage.

Sprouts appear to have generated 40% of the food-borne illnesses in outbreaks. These are supposed to be produced under conditions of control, cleanliness and sterility beyond any conceivable controls in the most aggressive sterile-farmscape models of agriculture. The sole "farm" inputs that have to be considered are (a) seeds and (b) potable water quality, yet the systems fail and fail routinely, despite years of FDA guidances. If the FDA does not have the capacity to control contamination of packaged and shipped sprouts, it seems unlikely that it will succeed in regulating the more complex operations of farms for food safety.

At some point, the FDA has to consider the safety impact of pre-cut and packages themselves. The single most effective way of improving produce food-safety could be:

21. Ban the sale of pre-cut and packaged produce (until shown to be safe?).

That is, perhaps, what consumer groups should focus on, instead of small farmers "wanting exemption from food safety." If small farmers are to become a source of a produce outbreak, it seems to me that it will be be due to their acting like processors by bagging and sealing produce, not due to their farming operations. An outbreak is defined as two or more cases. Small farms seem to have managed to avoid being part of the outbreak record for the last twenty years, although that could always change.

This is why both information and safe commodity-specific packaging material (with associated use-by information) could be so important for a broader range of growers.

Commingling of produce, processing in a common plant, and national distribution in complex packaging that may encourage pathogen survival and growth, while preventing visible spoilage, are all factors that increase the risks from the pre-cut processing industry. That the packaging itself may be an independent risk factor, even for the sole-grower cutting and packaging their own produce, needs to be addressed for farms of any size.

When I read the detailed investigation reports that are available, such as the Odwalla investigation and the 2006 spinach investigation, I see a reluctance on the part of some of the reporting investigators to use the same standards in implicating processing problems as they use for implicating wildlife, even though the processors have often taken steps -- ordinary or extraordinary-- to clean-up their plants before an investigation can

begin, which eliminates evidence as a side-effect. Yet the same reports still contain a record of serious errors in practice.

Odwalla, it appears, was processing apples from a supplier who had waxed downed apples, possibly sealing in pathogens, and then used an unusual wash solution -- as well as other steps that failed to implement their own safety policies. However, the report causally focused on the detection of O157:H7 in a single deer excrement sample of hundreds of environmental samples taken, despite it not having the outbreak strain.

This was irrelevant to Bill Marler's case against Odwalla, which focused on the strict liability of the food company and the failure to use the common industry safety practice of pasteurization. But it became summarized as "deer caused the Odwalla outbreak" as opposed to, say, "human error in processing controls caused the Odwalla outbreak."

The previous three U.S. O157:H7 cases, also in apple juice, had implicated domestic dairy cattle as probable sources of contamination. Two of these, like Odwalla, also had (for their times) state-of the art new processing equipment. One possible cause for investigation and reporting bias might be a kind of cognitive dissonance on the part of public health personnel: these are the good processors, using new equipment designed for food safety; these are the ones who work with us and take food safety seriously; it couldn't be their fault.

California State Senator Dean Flores, in contrast, repeatedly put up photographs of gross grower-shipper errors and processor violations in his hearings on the spinach crisis: portable outhouses located in the middle of leafy green production fields, "log-rolls" of spinach that would never be exposed to wash water and similar problematic practices.

What Bill Marler called the 2006 Dole Spinach outbreak did not involve a new plant; instead the supplier, Earthbound Farms / Natural Selection Foods had recently taken over operations of another processing facility as part of an expansion, and it was this plant which processed, packaged and shipped the bags associated with the outbreak (under multiple brand labels). Here again there were processing problems identified in the report by CFSAN and the California Department of Health (now DPH) such as using an unverified method of maintaining wash water quality and other facility failures.

The report was delayed for months, supposedly because of conflicts between CA DHS and CFSAN on what to report and what to conclude. In the end, there was no conclusion on the source of contamination, but the implication became common that "wild pigs caused the spinach crisis." However, when I look at the records, testimony in state hearings, and sometimes absence of records, it could have been something as simple as workers rinsing out the plastic totes in a (cattle contaminated) stream to save time at harvest; or failure to maintain equipment in the plant correctly, a tainted wash water source, health of management or employees, failure to provide adequate time for restroom breaks, and other processor errors, all of which have little to do with direct farming operations or wildlife.

UC Davis sampling of wildlife in the Salinas region since the outbreak has not found widespread contamination by O157:H7 (any strain, not outbreak strains); nearly zero for deer. This will be different for each pathogen, some are near ubiquitous. But the war on the natural environment on and surrounding farms represented by the buyer driven supermetrics was based on the assumption that wildlife causes food outbreaks by contaminating produce on farms, which processors are incapable of handling. All habitat that enhanced wildlife had to be destroyed.

In contrast, the “big pig hunt” that used to be joked about in Salinas and surrounding areas might be a more effective and selective control measure causing less environmental damage, since wild pigs had a 3% carrier rate of (unknown strains of) O157:H7. However, the prevention of contamination of water with human pathogens, and other possible vectors to the pigs, should be the primary approach.

It might be more reasonable to conclude that operational expansion of a processor, by itself, is a critical hazard period for food safety. The new plants in the New England apple juice cases were investments that probably required higher volumes. Odwalla was in a rapid growth phase as a national marketer when it built its new plant. Earthbound had acquired operational control of a second plant because of their rapidly expanding business. Any expansion represents tremendous commercial pressure on managers of processing facilities. Operational commercial pressure can overwhelm safety standards in many industries, not just food processors. Part of this pressure, which impacts food safety, could be mitigated by a safe harbor provision in commercial contracts.

It seems to me that we should be particularly concerned by the impact of the selection and evolution of more dangerous human pathogens like the STEC E.coli and antibiotic resistant strains that can transfer genetic material “horizontally” across species and rapidly. Its not known how long these human pathogens persist in the environment. We should know that constant introduction of them into the farm and farm environment is not helpful and needs to be controlled. The problem is not cattle, or dairy cows or other animals per se, in animals production but how they are raised and produced and how their products and byproducts are handled, and whether environmental contamination by human pathogens from these sources is controlled.

There is a similar issue with human derived contamination, of water for example, including from septic and water processing systems. In addition, asymptomatic persons can be carriers of STEC E. coli and other pathogens. All of this indicates the need for greater attention to people as vectors.

Even if wildlife is finally shown to have been a vector of pathogen contamination in some first case (birds on romaine?) the question is do you kill all the birds and remove all the bird habitat near a farm or move on to look at the source of the pathogen that contaminated the birds and whether this can be controlled (perhaps at the cattle operations twenty miles away).

The day may come when a grower implicated in a food outbreak will use the DNA data to sue all the animal production facilities where that unique strain is found to be harbored. Perhaps then we will start to get adequate regulation of pathogen introduction in the farm environment, if not before.

It doesn't take many decades of agricultural experience to realize that the two major political parties have different approaches to regulation. It sometimes seems that the Democrats have never met a regulation they don't like, even if it doesn't work. They may even like it better if it doesn't work. The Republicans, on the other hand, have never met a regulation that they like. Unless it increases the oligopoly power of the larger corporations by acting as a barrier to entry; or if the industry (like the biotechnology industry) demands it to smooth the pathway to commercialization, reduce competition by a barrier to entry, and provide cover against lawsuits.

Ideally, regulation would only occur when it is needed, specific, effective, addresses the issue of concern, leaves the innocent alone, and recognizes the limitation of the agencies supposed to enforce it. Food safety regulations based on commodity specific regulation seems to me to combine the worst aspects of both parties' approaches to regulation.

The USDA's Economic Research Service (ERS) provides detailed statistics on farms, farm numbers and farm size by commodity, but not by use for pre-cut. Farm size and production distributions are highly skewed statistically so that one cannot speak of an average farm with any meaning. A relatively few farms 2-10% depending on crop, dominate in the production of produce for the national market and are the main suppliers of pre-cut. For some crops, when I studied this two years ago, a single farm operation may make up 25-50% of a precut fresh market.

Regulating pre-cut farmers is a way of protecting the vast majority of farmers, who have not been involved in outbreaks, from the regulation that may be needed for the largest farms, who have been involved as a class in pre-cut outbreaks. It respects the farmers as independent actors who have as much to contribute to an understanding of food safety as any group of regulators. Because good farming requires detailed, local and historical knowledge, farmers may arguably have more to contribute to food safety than any other group. Give them relevant and accurate information and food safety objectives, first.

If a farmer, of any size, wants to produce for this higher risk market, they would need to meet the regulations designed for this higher risk use. It may be that very large field size is required to meet both food safety standards and environmental laws for pre-cut production: by minimizing contact between production and habitat, and minimizing the economic relative loss of production area (%) from buffers when needed.

It is ironic, perhaps stupid beyond belief, that produce safety regulation is being designed for the benefit of the agricultural sector that has caused the most outbreaks, and then will be 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 intent of these comments is to provide one alternative framework for proceeding with produce safety. There may be better alternatives, as well. I suggest that the FDA, HHS and USDA need to change directions towards one of these alternative paths towards produce safety