

April 7, 2008

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods
Docket No. 2007D-0494

On behalf of our member companies, United Fresh Produce Association (“United Fresh”) appreciates the opportunity to comment on the Draft Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated and Frozen Ready-To-Eat Processed Foods (“Guidance”). United Fresh applauds FDA on the change in regulatory policy implied in this Guidance, which better reflects current scientific understanding of the relative risk of listeriosis from exposure to low levels of the pathogen. Further, much of the Guidance reflects practices already in use for a number of processed commodities to ensure control of *L. monocytogenes*.

However, for fresh and fresh-cut fruits and vegetables, the broad brush approach of applying these guidelines to all FDA-regulated ready-to-eat processed foods will have dire and, we assume, unconsidered consequences to fresh-cut produce. And while FDA has emphasized the non-mandatory nature of the Guidance, reality is that it will be interpreted by many as mandatory.

First, we would like to speak to the apparent level of risk of fresh and fresh-cut produce as a vehicle for *L. monocytogenes* and listeriosis.

- The Guidance states, twice, that fresh raw produce is a potential source of *L. monocytogenes*. While we agree that any raw agricultural commodity (RAC) is a potential source of *L. monocytogenes*, we are unaware of any systematic surveys of commercially grown raw fruits and vegetables that demonstrate *L. monocytogenes* detection to be anything but rare or occasional. Indeed, if FDA considers RACs to be a significant source of *L. monocytogenes*, why does the Guidance exempt RACs, referring control to the 1998 Good Agricultural Practices guidance which, in turn, does not even mention *L. monocytogenes* as a significant pathogen of concern?
- The 2003 edition of the USDA/FDA/CDC Listeria Risk Assessment, table VII-1, describes raw fruits and vegetables as a moderate risk, based primarily on reports of detection of *L. monocytogenes*, not on linkages to illness. We note that the Assessment is silent on how many, if any, of these detections were from commercially fresh-cut, processed fruits and vegetables. In 2000, FDA helped to fund a survey of retail foods, in order to better understand the prevalence of *L. monocytogenes* in certain ready-to-eat foods [Gombas, D.E. et al. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. Journal of Food Protection 66:559-569]. Fresh-cut leafy green bagged salads, the most common form of commercially fresh-cut produce, were included in that study. By the end of that study, almost 3000 retail fresh-cut salad samples had been tested for *L. monocytogenes*. Less than 1% of those samples had detectable *L. monocytogenes*, the second lowest in prevalence among 8 ready-to-eat foods. Only one of the 3000 samples had a level greater than 100 cfu/gm and none had greater than 1000 cfu/gm. These samples, collected over 2 years, included retail packages at all stages of commercial shelf-life. Concurrently, CDC did not report any illnesses linked to fresh-cut leafy green bagged salads. We consider these data

as evidence that *L. monocytogenes* is a hazard not reasonably likely to occur in fresh-cut produce at levels likely to cause illness, even in the absence of many controls recommended in this Guidance.

- We are therefore surprised that FDA thought it important to specify in the Guidance that these guidelines should be followed by processors of fresh-cut fruits and vegetables, in spite of these survey data, the fact that many fresh-cut products - particularly fruits - are too acidic to support the growth of *L. monocytogenes*, and that many fresh-cut fruits and vegetables have never been reported to test positive for *L. monocytogenes*.
- For further evidence of the level of risk, we turn to past outbreaks of listeriosis linked to foods. Table II-4 of the 2003 USDA/FDA/CDC Listeria Risk Assessment indicates no reports of listeriosis outbreaks in the U.S. with a possible linkage to raw vegetables since 1979. Table II-5 indicates no reports of listeriosis outside the U.S. with a confirmed linkage to raw vegetables since 1981. Neither table includes any outbreaks linked to commercially prepared fresh-cut products. If one were to look at outbreak data over just the last 25 years, since the appearance of these products in the marketplace, commercially-prepared fresh fruits and vegetables would not even appear on the list. So, we again confess surprise that FDA, which has cited *Salmonella* outbreaks linked to tomatoes and melons, and *E. coli* O157:H7 outbreaks linked to leafy greens, as reasons for those fresh produce commodities to be considered higher risk, has foregone epidemiological evidence and simply declared fresh-cut produce to be at risk simply because *L. monocytogenes* can be detected on some raw produce and can be made to grow in some fresh-cut products.
- While this guidance refers to raw produce as a potential source of *L. monocytogenes*, food industry experience has shown that the processing plant environment is a more likely source of contamination. Several United Fresh member companies have hosted tours of their fresh-cut operations for FDA CFSAN scientists, to provide a real-world perspective. Those scientists saw that a typical fresh-cut operation is maintained at temperatures less than 40°F, has limited if any protein-based foods in the processing environment, and is cleaned and sanitized daily. We know that *L. monocytogenes* can grow in such an environment, but its growth will be slow. Anecdotal reports from processors that monitor their processing environment indicate that, while transient *Listeria* may be detected, recurring, entrenched niches – the typical source point for *Listeria* in the processing environment – do not occur in fresh-cut operations.

Now we would like to turn to the unconsidered consequences of these guidelines.

- The Guidance states in section IX, correctly, that “testing a single lot of a food product for *L. monocytogenes* is of limited value in establishing the acceptability of that lot”. But the same section recommends, if a processor’s raw materials may be a source of *L. monocytogenes*, that the processor either obtain a certificate of analysis (i.e., test results) from the supplier or perform its own testing of “every lot of that ingredient”. Since FDA has said in this guidance that raw produce is a likely source of *L. monocytogenes*, and there is no process step in Good Agricultural Practices or otherwise that will guarantee an absence of *L. monocytogenes* in harvested raw produce, let alone a 6 log listericidal treatment as described in section VIII, we can only conclude – as will others – that FDA intends for all lots of incoming raw produce to be tested for *L. monocytogenes*.
- The guidance also recommends that food contact surfaces be tested weekly for *L. monocytogenes*. We note in section XX that FDA agrees with us in our recommendation that, whenever an ingredient, finished product or food contact surface is tested for a pathogen or other food safety hazard, all lots of material impacted by that test should be segregated and held from use or distribution until cleared by a result of “not detected”. Please be aware that such materials

must be segregated and held regardless of an expectation that the test result will be “not detected” time after time. If a positive is reported – real or false – if the affected product has been shipped, it will likely be subject to a Class I recall with all of its consequences.

- The FDA’s BAM method for *L. monocytogenes* detection requires 2 days for an initial negative result, and up to an additional 5 days if the sample tests presumptively positive. Because *L. monocytogenes* has not generally been considered a pathogen of concern in fresh produce, we are unaware of rapid tests for the pathogen that have been validated for fresh produce items. However, based on rapid methods for other pathogens, such a test would likely take 24 hours for an initial negative, and again up to 5 days for a confirmed negative if the sample should test presumptively positive. This means that a processor has to be prepared for, and may need to, hold all raw produce ingredients and many finished product lots up to seven days each before release. Given that some produce items have a shelf life of 2 weeks or less, such a test and hold process could effectively eliminate those products from commercial viability. Even if the ingredients or products have sufficient shelf life that they could survive such testing, the capital costs for storing those tested materials in a refrigerated, secure environment until the results are known, and the loss of nutritional and organoleptic quality during that hold period, may also eliminate fresh-cut products from commercial viability.
- One of the food safety advantages of fresh-cut produce is rapid turnover, from the field to the processor to the consumer. If *Listeria* are actually present on the fresh produce ingredients, but not detected by testing, then a routine test and hold protocol will have given the *Listeria* an additional 2 to 7 days to grow.

Let us be clear – no one in the produce industry wants to sell products that may pose a health risk to consumers, and these would be important considerations if evidence demonstrated that *L. monocytogenes* and listeriosis were significant risks in fresh-cut produce. However, at this time and since the commercial inception of these products in the 1980’s, the types of controls and testing protocols described in the Guidance have not been generally implemented by the fresh-cut industry, yet there is no epidemiologic evidence of listeriosis linked to these products. If the fresh-cut produce industry were to implement the testing protocols described in the Guidance, the category may disappear. We respectfully submit to FDA that, while the testing recommended in the Guidance may be appropriate for some ready-to-eat processed foods, they could kill the commercialization of fresh-cut products.

Finally, United Fresh would like to describe how the fresh-cut produce industry might be guided to control for *L. monocytogenes* in a practical manner and commensurate with its apparent risk in fresh-cut products. First, as described in FDA’s recent *Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables* (“Guidelines for Fresh-cut”), fresh-cut processors should source their produce ingredients from reputable sources that utilize Good Agricultural Practices. Then, they should use inspection, culling, trimming and washing, as appropriate to the product, to eliminate dirty, bruised, decayed and questionable portions of the ingredient lot. Fresh-cut processors should have performed a hazard analysis, as part of a documented HACCP plan, to assess the potential risk of *L. monocytogenes* and, if deemed significant, identify appropriate control measures. Such processes have been implemented to control potential contamination by *Salmonella* and *E. coli* O157:H7 and should, on a commodity- or facility-specific basis, suffice for control of *L. monocytogenes* on incoming produce ingredients. Note that the industry’s current environmental controls appear to have been effective even without the additional, extensive efforts suggested in the Guidance, such as separate sets of fork lifts, carts and other equipment for raw and finished product, separate locker and cafeteria facilities for raw and finished product workers, and HEPA-filtered,

positive pressure air flow controls for processing areas. While some facilities' hazard analyses may deem these controls useful or necessary, we do not believe such controls are warranted on a routine basis.

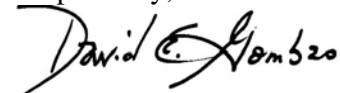
If a facility's hazard analysis concludes that *L. monocytogenes* is a hazard reasonably likely to occur in the processing environment, we suggest, instead of reliance on extensive routine ingredient, food contact surface and finished product testing, the facility first consider implementation of equipment and facility sanitary design controls such as described in the FDA Guidelines for Fresh-cut, and a prerequisite environmental monitoring program such as described by Tompkin *et al.* in 1999 (referenced in the Guidance). In that paper, the authors described a zone monitoring program that routinely tests non-food contact surfaces in the processing environment for potential encroachment and harborage of *Listeria* species. Those authors recommended performance of repeat and more in-depth testing of sites that test positive, to ensure that the positive was not transient and, if positive again, to better identify the niche. If the environmental tests demonstrated an entrenched *Listeria*, they recommended testing product contact surfaces and/or product for *L. monocytogenes*.

The fresh-cut industry stands ready to work with FDA on developing such recommendations into more detailed guidance, but we see such an approach as a risk-based response to the potential for fresh-cut product contamination by *L. monocytogenes*. Since this is largely what the fresh-cut industry has been using to date, such an approach appears to have been successful in managing the risk, and still allows for high quality, nutritious, and commercially viable products.

United Fresh Produce Association is the industry's leading trade association committed to driving the growth and success of produce companies and their partners. United Fresh represents the interests of member companies throughout the global, fresh produce supply chain, including family-owned, private and publicly traded businesses as well as regional, national and international companies. The association was founded in 1904 to represent the produce industry, and recently took the name United Fresh as a result of the 2006 merger of the United Fresh Fruit & Vegetable Association and the International Fresh-cut Produce Association.

Please contact me if United Fresh can provide clarification to any of these comments, or otherwise assist FDA in the further development of this Guidance.

Respectfully,



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