July 26, 2017

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852


Dear Sir or Madam:

On behalf of our members, the Produce Marketing Association (PMA) is respectfully submitting the following comments to the United States Food and Drug Administration’s (FDA) regarding FDA’s Revised Draft Guidance to Industry entitled: “Control of Listeria monocytogenes in Ready-To-Eat Foods” [Docket No. FDA-2008-D-0096]. To assist both FDA and our PMA membership in traversing the comments made here, we have organized our comments into specific categories and excerpted and referenced relevant passages from FDA documents in blue print with yellow highlighting for emphasis, to provide context to our comments. Below are comments detailing PMA’s activities and recommendations regarding this draft guidance to industry.

PMA is the largest produce trade association representing companies in the fresh fruit and vegetable industry. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate throughout the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

PMA’s vision is to strengthen and lead the global produce community to increase produce consumption. Fruits and vegetables are an integral part of a nutritious and healthful diet, offering great public health benefits. PMA believes that produce safety, taste, convenience, and nutrition are the cornerstones of increasing fruit and vegetable consumption and fighting obesity, diabetes and other chronic diseases. PMA also strongly advocates for sound produce safety public policy, that is practicable for our industry members to implement and that assures consumer confidence in the food supply.
Recent produce associated foodborne illness outbreaks and product recalls have made the produce industry acutely aware of the potential adverse public health consequences that can be associated with *Listeria monocytogenes* (Lm) and fresh produce. Fresh produce poses a unique challenge among FDA regulated foods in that: 1) most produce items do not receive a listeriacidal treatment before consumption, 2) produce items may or may not support Lm growth, 3) preventive controls to eliminate the presence of Lm where produce is grown are very limited and 4) fresh produce is likely to have a low persistent prevalence of Lm. However, we also acknowledge that control of Lm must be assessed and addressed during development and implementation of preventive controls for fresh produce during postharvest handling and fresh-cut processing. PMA acknowledges the importance of preventing listeriosis and has been actively engaged in a number of activities to facilitate this objective.

**PMA Activities**

In June 2015 PMA convened a Produce Safety Policy Conference in the Washington D.C. metro area to foster science and risk based produce safety policy discussion and build consensus on steps that can be taken to reduce, control or eliminate the risk of listeriosis associated with fresh produce consumption. As such, PMA convened subject matter experts from academia, the produce industry and government. Specifically, an outcome of this conference was the development of road map to reduce the public health risk of listeriosis from fresh produce consumption. The conference participants came to a general consensus on a number of recommendations and developed a policy roadmap and action plan regarding produce Lm preventive controls, education/outreach and research objectives to reduce, control or eliminate the risk of listeriosis associated with fresh produce consumption.

**PMA / United Fresh Joint *Listeria monocytogenes* Working Group**: Believing that produce-specific Lm issues can be best addressed through a collaboration, PMA and the United Fresh Produce Association in September 2016 convened a Joint Lm Working Group to address produce industry food safety concerns regarding Lm via coordinated education outreach, research and regulatory policy advocacy. This group has met regularly to share knowledge regarding means of reducing the risk of listeriosis across all produce industry segments. Specifically, the working group has engaged in the following activities:

**Education Outreach:**

- **Compilation & Communications of Available Information**: the working group has compiled and posted on line an extensive [resource list](#) to assist produce companies understand and control the risk of Lm in packinghouses and fresh-cut processing plants.

- **Lm Workshop**: the working group has developed a curriculum, recruited speakers and planned a two day “*Listeria monocytogenes* Intervention and Control Workshop for the Produce Industry” scheduled for July 18-19, 2017.

**Research:**

- **Research Priorities**: the joint working group performed a gap analysis to identify high priority key produce safety research needs for the produce industry with special emphasis on packinghouses and fresh-cut processing. This information was shared with the Center for Produce Safety and many of the identified research topics were incorporated into the Center for Produce Safety 2017 request for proposals and are likely to be addressed in future CPS funded research projects.
Regulatory Advocacy:
- PMA, United Fresh and other allied food and beverage industry trade organizations are working collaboratively via the Alliance for Listeriosis Prevention (ALP) to share knowledge regarding means of reducing the risk of listeriosis across food industry segments.
- The Alliance for Listeriosis Prevention in collaboration with IAFP hosted a webinar in February 2017 that was widely attended by the food industry. This webinar informed stakeholders about the recently published FDA Draft Lm guidance to industry.

FDA’s Draft Guidance Approach
In general, PMA concurs although with some reservations with FDA’s overall approach that is outlined in the FDA Draft Lm guidance to industry, in that we believe that a regulatory environment that encourages environmental monitoring for *Listeria* indicators is what is required to facilitate the use of science-based preventive control strategies to control Lm in ready-to-eat foods such as fresh produce. The draft proposed FDA approach does encourage food facilities proactively seek out and correct potential Lm harborages on food contact surfaces and non-product contact surfaces. The approach proposed in this FDA draft Lm guidance also aligns well with the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) “Compliance Guidelines to control *Listeria monocytogenes* in post-lethality exposed tread-to-eat meat and poultry products”. This alignment of FDA and USDA FSIS approaches to environmental testing for *Listeria* especially in dual jurisdiction food facilities is to be applauded.

The FDA draft Lm guidance provides regulatory flexibility that encourages the use of the “seek and destroy” strategy when transient positive detections of *Listeria species* or *Listeria*-like organisms occur. A significant element of this approach is the ability of industry to “seek and destroy” Lm through environmental monitoring as a verification measure.

We concur with following FDA recommendations in the draft Lm guidance regarding environmental monitoring:
- It is appropriate to use *Listeria spp.* as an indicator for Lm.
- A finding of *Listeria spp.* does not mean that Lm is present.
- An initial finding of *Listeria spp.* should not trigger an automatic requirement for speciation, but should trigger corrective action.
- In the absence of additional data, the finding of an isolated positive for an indicator on a product contact surface does not render product adulterated.

Fresh Produce Has Unique Challenges
Fresh produce poses a unique challenge among FDA regulated foods in that Lm is a microorganism that is routinely found in the outdoor/farming environment and its occasional transient detection on fresh produce in low prevalence and low numbers does not necessarily indicate poor practices or that a contamination event has occurred due to insanitary conditions or practices. It is not possible as a practical matter to have a zero tolerance for *Listeria monocytogenes* on fresh produce raw agricultural commodities due to the pervasive prevalence of Lm in the open environment where most produce is grown and harvested. Fresh produce raw agricultural commodities are also used as ingredients in fresh-cut produce processing. Since fresh-cut produce processing does not have a listeriacidal treatment, this means that fresh-cut produce will almost invariably on occasion contain a low number and prevalence of *Listeria monocytogenes* which cannot be completely avoided or prevented.
We at PMA believe that control of Lm should be considered and addressed during development and implementation of preventive controls for fresh produce postharvest handling and fresh-cut processing. However, there are no known preventive controls that can be implemented to reduce, control or eliminate Lm on fresh produce during growing operations in open fields. Transient Lm may contaminate fresh produce in the fields were produce is grown. In turn, these transient Lm can be introduced into the postharvest handing and fresh-cut processing environment and become resident Lm if they find appropriate niches and harborage where they can survive and thrive. Resident Lm can and should be controlled, reduced or eliminated via preventive controls in postharvest handling operations and fresh-cut produce processing operations. However, interpretation of ingredient testing, environmental monitoring and finished product testing results is very difficult for fresh produce operators whom have no listeriacidal treatment in their operation. This is because results from environmental monitoring and finished product testing results cannot quickly and cost effectively differentiate between transient Lm which contaminated product in the field versus resident Lm that has established itself in their packinghouse or fresh-cut processing operation.

**Environmental Monitoring Programs:** PMA supports the use of science- and risk-based environmental monitoring for *Listeria spp* to assist operators in identifying resident *Listeria spp* niches within produce operations, which may provide opportunities for *Listeria monocytogenes* to reside and persist. Environmental monitoring assists operators in identifying opportunities for improvement in equipment and building sanitary design, as well as needed improvements in cleaning and sanitation programs, or improved implementation of cleaning and sanitation programs.

The proposed FDA approach outlined in the Lm guidance encourages firms to perform environmental monitoring of food contact surfaces without causing adverse regulatory jeopardy is to be applauded. Some have characterized this as a “one bite at the apple” approach or “free pass”. This is most certainly is not a “free pass” as the initial test results require immediate corrective actions on the part of the firm. This is because if a second environmental monitoring positive occurs on that same or nearby food contact surface, the firm will almost certainly be in a full stop production mode. This “full stop mode” is especially true for the fresh produce industry as fresh produce is extremely perishable and it cannot be put on a test and hold program.

FDA has opined extensively on the issue of the value and utility of environmental monitoring in produce operations that handle raw agricultural commodities:

> We are not requiring environmental testing for *L. monocytogenes* or *Listeria spp.* for covered produce other than sprouts. See discussion in the 2013 proposed rule (78 FR 3504 at 3619). Farms may consider voluntarily performing environmental testing for *L. monocytogenes* or *Listeria spp.* as appropriate for their operations. See also section VII of this document where we discuss farm-specific food safety plans. (FSMA Final Produce Safety Rule Preamble Response 11 / pg 74364)

> Environmental testing for *L. monocytogenes* or *Listeria spp* for covered produce other than sprouts—Proposed § 112.143(a) would require testing the growing, harvesting, packing, and holding environment for sprouts for *Listeria species* or *L. monocytogenes*; however, we have not proposed to require environmental testing for other covered produce. A recent outbreak of listeriosis from cantaloupes attributed to insanitary conditions at a facility that washed, packed, cooled and held intact cantaloupes (Ref. 267) raises the question as to whether specific measures are necessary to minimize the risk posed by *L. monocytogenes* as an environmental pathogen. As discussed in section V.A. of this document, this proposed rule would not apply to offfarm facilities.
such as the facility associated with this cantaloupe outbreak—such facilities would instead be subject to part 110 and may be subject to section 418 of the FD&C Act. However, the same risk factors and potential measures for minimizing risk are relevant to both on-farm and off-farm produce washing, packing, cooling, and holding practices. Such measures could include environmental testing for *L. monocytogenes* or *Listeria* spp. to verify the adequacy of a covered farm’s sanitation measures. Because *L. monocytogenes* is a ubiquitous microorganism, an intact fruit or vegetable could reasonably be expected to occasionally be positive for *L. monocytogenes*. Many studies have shown the presence of *L. monocytogenes* on fresh, intact produce, but there is limited epidemiological evidence associating listeriosis with produce, especially with intact fruits and vegetables (Ref. 268, Ref. 269, Ref. 270, Ref. 271, Ref. 272, Ref. 267). However, this recent outbreak indicates that intact produce can be a vehicle for listeriosis. What is not known is the extent to which, and under what circumstances, whole produce contaminated with *L. monocytogenes* presents a risk to consumers. The outbreak of listeriosis due to contamination of intact cantaloupes appears to have occurred due to a combination of factors, including pooled water on the floor of the facility, which was also difficult to clean, poorly designed equipment that was previously used for other commodities, no pre-cool step, a truck parked near the packing area that had visited a cattle operation, and possible low-level contamination from the growing/harvesting operation (Ref. 273). The contribution of internalization of the organism and growth within the fruit is not known. Moreover, it is not known whether all of these circumstances are needed for *L. monocytogenes* to present a risk on produce or whether any one or more would have been sufficient. We also do not know the prevalence of *L. monocytogenes* environmental contamination of fruit and vegetable packing facilities (both on- and offfarm), nor do we know the prevalence of *L. monocytogenes* on produce washed, packed, cooled and stored in such facilities. We encourage research to answer these questions. We request comment on whether we should require, in a final rule, any or all covered farms that wash and pack produce, or that only pack produce, to perform environmental testing for *L. monocytogenes* or *Listeria* spp., and any criteria that should be employed to determine which farms should be subjected to such a requirement.

(Federal Register /Vol. 78, No. 11 /Wednesday, January 16, 2013 / Proposed Produce Safety Rule pg 3619).

- We expect that many facilities that process, pack, or hold produce RACs that are RTE foods may conclude, as a result of their hazard analysis, that neither product testing nor environmental monitoring is warranted.
- We also expect that many facilities that process, pack, or hold produce RACs that are RTE foods will conclude that the limitations of product testing when applied to produce reduce the value of product testing for their products and would direct their resources to food safety practices and verification measures other than product testing.
- In addition, we expect that some facilities will see benefits in conducting environmental monitoring as a verification measure and would direct resources to such activities.

(Final PCHF Rule Response 525 / pg 56062)

However, the current FDA Revised Draft Guidance for Industry “Control of *Listeria monocytogenes* in Ready-To-Eat Foods” is currently silent in providing guidance regarding how firms are to effectively address Lm risk for unwashed RTE produce RACs. See detailed comments below.

**Produce Finished Product Testing**

FDA has opined extensively on the issue on the value and utility of finished product testing for farms that handle produce raw agricultural commodities. (see below)
We are concerned with FDA’s recommendation put forward in the FDA draft Lm guidance for firms to conduct finished product testing for the presence of *Listeria monocytogenes*, as the recommendation is inconsistent with FDA’s approach to finished product testing in the FSMA Produce Safety Rule.

*We tentatively conclude that product testing would be impracticable as a component of science-based minimum standards proposed in this rule* except as set forth in proposed subpart M under certain circumstances for sprouts.

(Federal Register /Vol. 78, No. 11 /Wednesday, January 16, 2013 / Proposed Produce Safety Rule pg 3533)

Finished product testing can provide useful information on the overall risk of a food when pathogens have been detected in the environment.

(Federal Register /Vol. 78, No. 11 /Wednesday, January 16, 2013 / Proposed Produce Safety Rule pg 3600)

FDA in the final FSMA Produce Safety rule concluded that finished testing is of very limited value, with the exception of sprouts. PMA concurs that final product testing is of very limited utility and should not have been included in the final produce rule and has commented as such. Furthermore, there are several technical, operational and product quality challenges surrounding fresh produce product finished product testing, including: the challenges of testing fresh produce items because of their highly perishable nature and complex composition; the selectivity and sensitivity of the pathogen tests commercially available; the question of whether to test raw or finished products; and, the challenges surrounding effective and significant product sampling. In developing a food safety plan produce packinghouse operators and fresh-cut processors do assess hazards and develop controls to manage their risks. Testing should focus on evaluating the success of the controls in managing the risk. Product testing may identify an issue at a point in time but it will not identify the cause or contributing factors. Preventive controls and critical control points are more effective and informative of product safety on a regular basis. Limited food safety resources available to a packinghouse or fresh-cut processing plant operator are best utilized and most effective at reducing produce safety risk by implementing preventive controls not testing products. Finished product testing takes valuable resources away from implementing food safety programs and may offer a false sense of security.

**FDA Lm Zero Tolerance Policy**

The FDA has publicly stated that the basis for its Lm “zero tolerance” policy is derived from new information from recent foodborne illness outbreaks (e.g. Blue Bell Ice Cream) and a new dose response model developed by Pouillet *et al*, 2015 and published in the journal Risk Analysis. However, it is unclear as to exactly how FDA has concluded that the FDA proposed (FDA 2008) 100 CFU Lm / g standard for RTE foods that do not support growth, is insufficiently protective of public health.

**Outbreak Data**

FDA data (Chen *et al*, 2016) demonstrate and document the prevalence and levels of Lm in ice cream from a food manufacturer that was associated with this listeriosis foodborne illness outbreak. This data indicates that a small percentage (0.2%) of product samples had in excess of 100 CFU Lm / g. It is currently unclear if the deaths associated with this food product were caused by ice cream which had low levels (<100 CFU/g) or elevated levels (>100 CFU/g) of Lm. Given the massive number of servings produced by this food manufacturer and the limited number of deaths associated
with this food product, one may conclude that only products with high levels were likely to cause mortality.

Lm Dose Response Revisited—Incorporating Adjustments for Variability in Strain Virulence and Host Susceptibility (Pouillet et al, 2015)
This publication is a well-executed and clearly written scientific document. The primary purpose of the study was to derive a novel framework and not to provide a definitive dose-response model for policy development. The authors also acknowledge that a definitive dose-response model would require refinements and additional data such as the relative risk of listeriosis among different population subgroups in the United States. Additionally, the authors clearly state that many assumptions were preferentially chosen to be conservative and public health protective, which biases the Lm dose response model and results in a higher probability of infection for low doses. Specifically, two key assumptions (neglecting bacterial growth from retail to consumption and capping the maximum level of contamination of Lm 6.1 log10 cfu/g), are not supported by the peer reviewed literature and create a significantly downward bias in the developed dose response model. As such any public health policies based on this dose response model would be highly conservative, not supported by the peer-reviewed literature and therefore inappropriate.

The Food Drug and Cosmetic Act adulteration provisions state that:
“A food shall be deemed to be adulterated—
(a) Poisonous, insanitary, etc., ingredients
(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.”

FDA may wish to consider that transient Lm on some foods such as RAC fresh produce is a substance not added and does not ordinarily render a food injurious to health as specified in the adulteration provisions of the FD&C Act. Lm resident contamination of food facilities is avoidable and as stated above appropriate preventive controls should be used by facilities handling fresh produce RACs and fresh-cut produce. However, Lm picked up on a farm orchard or field during growing operations may be considered an unavoidable adulterant that ordinarily does not render a food injurious to health. It is also important to again point out the fresh produce RTE RACs: do not receive a listeriacidal treatment before consumption and preventive controls to eliminate the presence of Lm where produce is grown are very limited and thus fresh produce is likely to have a low persistent prevalence of Lm.

Conclusion
PMA looks forward to collaborating with FDA to continue to protect U.S. consumers, particularly those most susceptible to infection; through targeted interventions and the application of guidance and policies that are conducive to aggressively address the potential for Lm environmental contamination. We thank FDA for the opportunity to provide public comments regarding this important food safety issue as we share the common goals of setting a high bar for food safety and providing a practicable regulatory framework for the produce industry. It is recommended that FDA after careful review of received stakeholder comments either amend and finalize this draft guidance or withdraw it. It is important that this draft guidance to industry in its current un-amended form not linger in an
unfinished state for a prolonged period, as in absence of final guidance many entities may interpret this draft guidance as FDA’s current and best thinking on the issues opined up within this guidance.

Respectfully,

[Signature]

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Detailed Comments

Produce is a RTE Food

*Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

(Excerpted from Preventive Controls for Human Foods Rule § 117.3 Definitions)

*Ready-To-Eat (RTE) Food:* The terms RTE food and RAC are not mutually exclusive. Some RACs (such as lettuce, tomatoes, berries, and apples) are ready-to-eat, whereas other RACs (such as artichokes and potatoes) are not. The requirements for product testing as a verification activity are flexible requirements that depend on the facility, the food, and the nature of the preventive control (see § 117.165). See also Response 525.

(Excerpted from Preventive Controls for Human Foods Rule Response 122 / pg 55955)

Comments: The FDA Revised Draft Guidance for Industry “Control of *Listeria monocytogenes* in Ready-To-Eat Foods” as per its title applies to Ready-To-Eat (RTE) foods. FDA’s defines a RTE food in 21 CFR § 117.3 and provides context regarding its application to raw agricultural commodities in the preamble of the Preventive Controls for Human Foods rule. (see above)

The current FDA definition of a RTE food is inadequate in that it does distinguish among different categories and types of RTE foods that may have a significantly different Lm risk associated with them.

For example, the following three products are by the current FDA definition all RTE foods:

- An unwashed whole produce RAC, packed off farm in a Sc1ence#registered food facility / packinghouse – no listeriacidal treatment / may or may not support Lm growth
- A washed fresh-cut produce item – mild listeriacidal treatment (i.e. washing) / may or may not support Lm growth
- A frozen cut produce item that has been subjected to a validated listeriacidal blanching step – robust listeriacidal treatment / does not support Lm growth when frozen.

These three RTE foods are produced in FDA registered food facilities and are subject to coverage by 21 CFR 117. However, the FDA Revised Draft Guidance for Industry “Control of *Listeria monocytogenes* in Ready-To-Eat Foods” does not fully acknowledge or fully incorporate a commensurate or scaled approach to risks posed by each of these products in its recommendations. In that, the actual level of Lm risk (i.e. the probability of illness) associated with each of these products is dependent on: initial exposure level of Lm (if present), Lm prevalence, changes in Lm populations (growth/no growth) and consumption (frequency & serving size).

Specifically, the current FDA Revised Draft Guidance for Industry “Control of *Listeria monocytogenes* in Ready-To-Eat Foods” is currently silent in providing guidance regarding how firms are to effectively address Lm risk for unwashed RTE produce RACs that:

- do not receive a listeriacidal treatment;
- may or may not support Lm growth;
- are likely to have a low persistent prevalence of Lm as they are grown in the outdoors;
• have no known preventive controls to control, reduce or eliminate the presence of Lm in fields or on fresh produce grown outdoors.

It is currently not possible for firms whom grow, harvest, pack, hold and/or fresh-cut process produce RACs to completely assure that transient Lm are not on produce items they introduce into commerce because of the reasons listed above. This fact coupled with FDA’s current zero tolerance level for Lm in foods is very problematic for this produce industry segment.

The fresh produce industry acknowledges that control of resident Lm in packinghouses and fresh-cut processing plants must be assessed and addressed during development and implementation of preventive controls for fresh produce postharvest handling and fresh-cut processing. However, the fresh produce industry has serious concerns regarding the potential regulatory jeopardy of a single transient Lm sampling finding on a produce RAC.

It is currently unclear as to the public health risk posed by sporadic Lm prevalence in very low numbers on produce RACs. However, the potential regulatory jeopardy of such a finding because of FDA’s current zero tolerance compliance and enforcement for Lm is clear. Unfortunately, this FDA zero tolerance compliance and enforcement policy means that the mere presence of Lm at any level is presumed to represent a potentially significant consumer risk.

It is suggested that FDA consider formulating an alternative risk based approach to this regulatory conundrum for fresh produce RACs. Specifically, it is suggested that FDA consider a compliance and enforcement policy that will give low priority allocation of agency resources and regulatory actions in situations where low prevalence and low levels of Lm are found on the surface of produce RACs (especially on non-growth RACs) as such findings likely represent low risk for the vast majority of consumers. Currently, the fresh produce industry is focusing on assuring that Lm is not being added to produce during harvest, postharvest handling and fresh-cut processing but the absolute absence of Lm cannot be guaranteed. The current FDA zero tolerance policy for Lm on foods such as RTE produce is aspirational but unattainable in practice. While every food producer strives for zero risk being associated with the foods that they manufacture, process, pack or hold, in some cases (e.g. produce RTE produce) it is not possible to attain zero risk. Therefore, we respectfully request that FDA re-evaluate its current zero tolerance compliance and enforcement for Lm in foods.

**Foods that support growth of Lm?**

Examples of RTE foods that support the growth of *L. monocytogenes* and that have been found to be contaminated with *L. monocytogenes* are unpasteurized and pasteurized milk, high fat dairy products, soft unripened cheese (Cottage Cheese, Cream Cheese, Ricotta), cooked ready-to-eat crustaceans (shrimp, crab), smoked seafood, fresh soft cheese (Queso Fresco), semi-soft cheese (Blue, Brick, Monterey), soft-ripened cheese (Brie, Camembert, Feta), deli-type salads, sandwiches, fresh-cut fruits and vegetables, and raw molluscan shellfish (Ref. 7, Ref. 26, and Ref. 27). An example of an RTE food that does not support the growth of *L. monocytogenes*, but has been found to be contaminated with *L. monocytogenes*, is ice cream (Ref. 28 and Ref. 6).

(Excerpted from DRAFT Lm Guidance Page 4)

**Comments:** PMA concurs with FDA that assessment of whether or not a food supports the growth of *Listeria monocytogenes* should be considered by firms when assessing the risk and development of appropriate preventive controls, procedures and practices for the manufacturing, packing and/or holding of a food. However, it is indeterminate as to exactly what FDA means by “growth of *Listeria monocytogenes*” and under what storage temperature conditions. Specifically, does growth mean
more than 1 log unit increase in *Listeria monocytogenes*? Many commonly employed test methods vary in accuracy by plus or minus 1 log unit. Hence most food microbiologists do not consider there to be any growth unless there is greater than 1 log increase in Lm populations in a food. Additionally, food storage temperature will greatly influence Lm growth and it is unclear if FDA is suggesting that firms consider whether or not a food supports the growth of Lm when a food product is stored at optimal, abusive or expected distribution temperatures. Therefore, PMA respectfully requests that FDA provide further details as to the criteria that FDA would use for determining whether or not a food product supports the growth of Lm. It is also suggested that FDA consider use of criteria such a rapid and prolific growth, and not just growth. Many foods will support slow Lm growth and this may be problematic for long shelf-life foods. However, slow Lm growth, although still growth, may need to be considered in very short shelf life perishable food items.

**Comments:** FDA has identified fresh-cut fruits and vegetables as being foods that support the growth of Lm. What definition and criteria is FDA using to define “fresh-cut fruits and vegetables” for the purposes of this guidance document? The definition and criteria used to define “fresh-cut fruits and vegetables” is important to assure that the produce industry clearly understands which products this guidance applies to. It should also be noted that not all fresh-cut produce supports the growth. For example, Farber et. al, 1998 found that fresh-cut shredded carrots do not support the growth of Lm. As such more research based on objective criteria are needed to evaluate what foods including which fresh-cut produce items do and do not support the growth of Lm. It is also suggested that the list of products listed in this paragraph be deleted as it is currently inaccurate. The determination of a food being an Lm growth or non-growth food should be left to be determined by the manufacturer/processor.

**Environmental Monitoring**

**PCHF Requirements**

Some PCHF requirements are expressly directed to *L. monocytogenes* and to RTE foods. For example, the definition of “environmental pathogen” identifies *L. monocytogenes* as an environmental pathogen (21 CFR 117.3), and the hazard evaluation required by 21 CFR 117.130 must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen (21 CFR 117.130(c)(1)(ii)). (Excerpted from DRAFT Lm Guidance Page 6)

**Comments:** As noted above 21 CFR 117.130 of the Preventive Controls for Human Food Rule requires that firms include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment. It is unclear as to why FDA has limited the applicability of this Guidance to Industry solely to firms that are covered by the Preventive Controls for Human Foods rule. Lm may exist in niches and harborages where raw agricultural commodities are packed or packaged and use of appropriate preventive controls, procedures and policies outlined in this guidance may in some cases be applicable to such produce operations that may be regulated by the FSMA produce safety rule. Produce packinghouses are actively making efforts to enhance their Listeria control programs and we believe that they would find the recommendation contained within this guidance applicable and useful. As hazards like Lm do not recognize any regulatory boundaries, it is suggested that FDA may wish to consider stating that the recommendations contained within this guidance may have applicability and warrant consideration by firms whom are covered by rules other than the Preventive
Controls for Human Food Rule. It is also suggested that this guidance may be of benefit foods not regulated by 21 CFR 117, such as those firms that are regulated by seafood HACCP.

Environmental Monitoring Program (EMP) Positive Test Results

A positive test result for the presence of Listeria spp. on an FCS or non-FCS indicates the potential for contamination of an FCS or non-FCS with L. monocytogenes and suggests that conditions are suitable for survival and/or growth of L. monocytogenes. A positive test result for the presence of Listeria spp. on an FCS or a non-FCS does not establish the presence of L. monocytogenes on an FCS or non-FCS.

(Excerpted from DRAFT Lm Guidance Page 36)

Comments: PMA concurs with the FDA accretion that a positive test result for the presence of Listeria spp on a FCS or a non-FCS does not establish the presence of Lm on a FCS or non-FCS.

EMP Sampling Frequency

We recommend that even the smallest processors collect samples from at least 5 sites of FCS and 5 sites of non-FCS on each production line for RTE foods. We recommend that larger processors determine the appropriate number of sampling sites based on the size of the plant.

(Excerpted from DRAFT Lm Guidance Page 36)

We recommend the lowest frequency (e.g., monthly) of routine sample collection be for those RTE foods that do not support growth of L. monocytogenes. We recommend that the highest frequency (e.g., weekly) of routine sample collection be for those RTE foods that support growth of L. monocytogenes. Frequency of sampling should be increased when Listeria spp. positive samples are found in the plant (see section on Corrective Actions).

(Excerpted from DRAFT Lm Guidance Page 37)

The most important time to collect environmental samples is at a time that is several hours into production (e.g., 3 to 4 hours) or preferably just prior to cleanup, because this allows time for L. monocytogenes (if present) to work its way out of harborage sites and contaminate the environment, the processing line (including FCS sites), and, potentially, RTE product. Note that if you take samples too close to the time when surfaces have been sanitized, the sanitizer may not be adequately neutralized and could interfere with the analytical test.

(Excerpted from DRAFT Lm Guidance Page 37)

An example of how to specify the frequency of sample collection in a written environmental monitoring plan for FCSs in an establishment producing an RTE food that supports growth of L. monocytogenes is as follows:

- Collect environmental samples from specific FCSs on the production lines at least once every week when the plant is in operation; and
- Test each FCS in the plant at least once each month.

An example of how to specify the frequency of sample collection in a written environmental monitoring plan for non-FCSs in an establishment producing an RTE food that supports growth of L. monocytogenes is as follows:

- Collect environmental samples from representative sets of non-FCSs at least once weekly for zone 2 sites, every two weeks for zone 3 sites, and monthly for zone 4 sites when the plant is in operation; and
- Test all non-FCS sites identified in the monitoring plan at least once each quarter.
Comments:

Frequency of Environmental Monitoring: It is unclear as to what the scientific basis is for FDA’s recommendation for firms as minimum to take 5 FCS & 5 NFCS for each line? Use of minimum numerical recommendations is overly prescriptive, as a fixed minimum number of samples may be insufficient in some circumstances or a waste of resources given other circumstances. Firms may choose to focus on certain pieces of equipment and/or locations where they have historically identified *Listeria spp* niches or harborage. Sampling schemes, frequency and numbers will be very firm and product specific as very small food operations may have only stainless steel tables as food contact surfaces versus others that have conveyor belts and other product conveyances. It is therefore suggested that FDA leave the number and frequency of environmental monitoring samples up to the discretion of the individual firms based on their hazard analysis. A firms environmental monitoring program should be science and risk-based and should take into consideration the firms procedures, policies, practices, product, facility conditions, amount of product, EMP history, etc. Additionally, FDA should consider that test results may require 48hrs, 72hrs or more to be reported and communicated to a firm. Therefore, environmental monitoring should be performed at a frequency which provides a firm with sufficient time to review test results and take corrective actions before subsequent environmental monitoring and testing occurs.

Defining a “production line”: It is unclear how FDA is defining what an individual “production line” is and we ask for further clarification. This is particularly pertinent to the fresh produce industry as multiple products may be manufactured/processed on the same equipment and often times equipment may be interchanged for specific products to be produced.

Produce Unique Challenges: The FDA recommendation to “collect environmental samples at a time that is several hours into production (e.g., 3 to 4 hours) or preferably just prior to cleanup, …” is problematic and impracticable for fresh produce operations to implement. Fresh produce operations have no listeriacidal treatment and raw agricultural commodities are expected to have a low prevalence of *Listeria spp* being processed on equipment. When a firm samples a food contact surface 3 to 4 four hours into a production run and gets a *Listeria spp* positive test result, the firm cannot easily or quickly determine if this sample finding is a resident or transient detection of *Listeria spp*.

PMA requests that FDA clarify that product does not need to be run for environmental monitoring to be conducted, in that machinery could be run without product passing through the system. Currently, the guidance implies that product must be running. We believe that effective environmental monitoring can be accomplished and provide comparable results if equipment can run without product, wherever possible. When firms can operate equipment without running product, there are two benefits. First, a positive test result is clearly tied to the equipment or facility, not a product. Second, it allays the previously mentioned concern around holding perishable products. We recommend that FDA revise the guidance to read (on p. 37) “The most important time to collect environmental samples is after equipment has been operational for several hours (e.g., 3 to 4 hours), because this allows *L. monocytogenes* (if present) to work its way out of harborage sites and contaminate the environment and the processing line (including FCS sites).” We believe this is preferable to situations where product may be contaminated, as is suggested in the draft guidance.
Do all FCS environmental monitoring results indicate an equal level of public health risk?

The recommendations put forward in this DRAFT guidance places an equal level of risk and required action on EMP results irrespective of where the positive EMP results are found. In that, FCS’s that are used to handle RACs before they are cut and washed during fresh-cut processing have an equal level of significance and required corrective actions as when a EMP L spp test results are found in a high care area after, for example, cutting and washing of a fresh-cut produce item. This is problematic. For example, it is likely that RAC’s entering a fresh-cut produce processing plant will have a low and sporadic prevalence of L. spp associated with any particular lot. Although fresh produce operations have no listeriacidal treatments some preventive controls such as use of wash water disinfectants used during washing produce can reduce or even minimize L spp prevalence and populations on FCS’s. Finding a L spp positive EMP test result in a high care area, that being post cutting and washing; is of much greater significance than finding a L. spp EMP positive on a dry dump conveyor belt used to unload RACs that are used as ingredients. Since the current FDA recommendation is to run equipment for 3-4 hours before taking an EMP sample, an operator will not be able to quickly and easily ascertain if the positive test result is due to a transient L spp being brought in on raw materials or if it is problematic resident strain of L spp. It is suggested that FDA consider addressing the relative significance of where EMP L. spp positive test results are found and have corrective actions associated with such finding be commensurate with the relative public health risk. EMP findings of L. spp on FCS’s that handle ingredients are not of equal significance to EMP findings of L. spp on FCS’s that are in high care zones (i.e. post application of listeriacidal treatments)

PMA recommends that the guidance direct users to focus their testing programs on areas of greatest risk. We do not believe fresh produce operations should conduct extensive environmental testing at the point of receiving, or in areas where dry product is being handled. Rather, we believe the greatest public health benefit will come from focusing resources on wet areas and areas that the testing program has identified as being problematic.

It is also recommended that the guidance should emphasize the relationship between the facility’s hazard analysis and the environmental monitoring program. If the hazard analysis of, for example, a dry packing operation, warehouse, or re-packing operation determines that the risk of contamination of L. monocytogenes is low, then they should not be expected to follow the testing recommendations in the draft guidance. We expect that operations that are washing fresh produce will often recognize the need to implement an environmental monitoring program.

As noted below, we believe that while the sampling frequency suggested in the draft guidance is an excellent starting point, a facility should tailor their program based on their own risk assessment, including their history of positives. Given the diversity of fresh produce packing and processing operations, there may be locations where risk could be higher due to the introduction of water, and points where risk may be lower because, for example, intact produce has been dried.

EMP Corrective Actions

§ 117.150 Corrective actions and corrections.
(a) Corrective action procedures. As appropriate to the nature of the hazard and the nature of the preventive control, except as provided by paragraph (c) of this section:
(1) You must establish and implement written corrective action procedures that must be taken if preventive controls are not properly implemented, including procedures to address, as appropriate:
(i) The presence of a pathogen or appropriate indicator organism in a ready-to-eat product detected as a result of product testing conducted in accordance with § 117.165(a)(2); and
The presence of an environmental pathogen or appropriate indicator organism detected through the environmental monitoring conducted in accordance with § 117.165(a)(3).

(Excerpted from Preventive Controls for Human Foods Rule)

Recommendations regarding your plant and your procedures
If you detect L. monocytogenes on an FCS, we recommend that you follow a risk-based corrective action procedure that describes the steps to be taken, and assigns responsibility for taking those steps, to ensure that the cause of the contamination is identified and corrected. We specifically recommend that your corrective actions regarding your plant and your procedures include the recommendations in section XIII.F.1 of this guidance. The goal is to find the source of contamination and eliminate it.

(Excerpted from DRAFT Lm Guidance Page 51)

Figure 1.—Example of Non-FCS* testing and follow up activities for Zone 2.

(Excerpted from DRAFT Lm Guidance Page 42)
G. Summary of Recommended Corrective Actions When You Detect Listeria spp. in an Environmental Sample

See Figure 1 in section XIII.E and Figure 2 in section XIII.F.1 for flow diagrams of examples applying the recommendations and example corrective action procedures discussed regarding your plant and your processing, including recommendations and example corrective action procedures for testing non-FCSs and FCSs, respectively, and for follow up actions based on the test results. Table 6 summarizes the recommended corrective actions when you detect Listeria spp. in an environmental sample.
sample taken from non-FCSs and FCSs. For each type of surface (i.e., non-FCS and FCS), Table 6 also compares the corrective actions for growth foods to the corrective actions for non-growth foods.

Table 6.--Corrective Actions when Listeria species is found in an environmental sample

<table>
<thead>
<tr>
<th></th>
<th>Non-FCS Food supports growth</th>
<th>Non-FCS Food does not support growth</th>
<th>FCS Food supports growth</th>
<th>FCS Food does not support growth*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Routine sampling</strong></td>
<td>* Clean and sanitize area of positive</td>
<td>* Clean and sanitize area of positive</td>
<td>* Clean and sanitize area of positive</td>
<td>* Clean and sanitize area of positive</td>
</tr>
<tr>
<td><strong>positive #1</strong></td>
<td>* Retest during next production cycle</td>
<td>* Retest during next production cycle</td>
<td>* Retest during next production cycle</td>
<td>* Retest during next production cycle</td>
</tr>
<tr>
<td><strong>Follow up sampling</strong></td>
<td>* Intensified cleaning and sanitizing (possibly including disassembly of equipment)</td>
<td>* Intensified cleaning and sanitizing</td>
<td>* Intensified cleaning and sanitizing</td>
<td>* Intensified cleaning and sanitizing (including disassembly of equipment)</td>
</tr>
<tr>
<td><strong>positive #2</strong></td>
<td>* Intensified sampling and testing</td>
<td>* Intensified sampling and testing</td>
<td>* Intensified sampling and testing</td>
<td>* Intensified sampling and testing</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* Hold and test product</td>
<td>* Reprocess, divert or destroy product on hold if there is positive product</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>* Comprehensive investigation</td>
<td>* Comprehensive investigation</td>
</tr>
</tbody>
</table>

* Conduct comprehensive investigation.
We recommend that corrective actions for non-growth foods specifically intended for establishments such as hospitals and nursing homes be similar to those for foods that support growth.

(Excerpted from DRAFT Lm Guidance Page 50-51)

<table>
<thead>
<tr>
<th>Follow up sampling positive #3</th>
<th>Root cause analysis</th>
<th>Root cause analysis</th>
<th>Stop production and consult experts for comprehensive investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-FCS Food supports growth</td>
<td></td>
<td></td>
<td>• Stop production and consult experts for comprehensive investigation</td>
</tr>
<tr>
<td>Non-FCS Food does not support growth</td>
<td></td>
<td></td>
<td>• Intensified cleaning and sanitizing (including disassembly of equipment)</td>
</tr>
<tr>
<td>FCS Food supports growth</td>
<td></td>
<td>• Intensified cleaning and sanitizing (escalated, e.g., steam equipment)</td>
<td></td>
</tr>
<tr>
<td>FCS Food does not support growth*</td>
<td></td>
<td>• Intensified sampling and testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hold and test product</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Expand comprehensive investigation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hold and test product</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reprocess, divert or destroy positive product lots</td>
<td></td>
</tr>
</tbody>
</table>

* We recommend that corrective actions for non-growth foods specifically intended for establishments such as hospitals and nursing homes be similar to those for foods that support growth.

(Excerpted from DRAFT Lm Guidance Page 50-51)
In general, there is minimal value in determining whether Listeria spp. detected on a non-FCS is L. monocytogenes, because you should eliminate the Listeria spp. regardless of whether it is L. monocytogenes. If you find Listeria spp. on a non-FCS or in the same general area on multiple occasions, we recommend that you conduct a root cause analysis to determine why this area continues to be a source of positive results and take actions to eliminate the contamination, such as by determining the efficacy of your sanitation procedures and modifying them as necessary. (See Analysis of Data for Trends in Section XV.)

(Excerpted from DRAFT Lm Guidance Page 43)

2. Determining whether Listeria spp. is L. monocytogenes

If an FCS tests positive for the presence of Listeria spp., we recommend that your corrective action procedures specify when to determine whether the Listeria spp. is L. monocytogenes. In general, the greater the risk of foodborne illness presented by the RTE food being produced on an FCS that has tested positive for Listeria spp., the greater the importance of determining whether any Listeria spp. you detect on an FCS is L. monocytogenes.

(Excerpted from DRAFT Lm Guidance Page 48)

Comments: PMA generally concurs with the recommendations put forth in the food contact surface environmental monitoring decision matrices, as these are generally accepted practices by the fresh-cut produce processing industry. However, we do have some clarifying questions and concerns that are produce specific:

❖ **Hold & Test for Perishables:** As fresh-cut processed produce is extremely perishable, it is impractical to implement a hold and test procedure when a second Listeria spp environmental monitoring positive sample occurs. Because of the lag time in test result reporting and subsequent loss of product shelf-life it is simply not practicable to hold product for 48-72 hours. Holding and testing some, fresh produce RACs may be possible due to longer shelf-life of some of these perishable products.

❖ **Product In Commerce:** It is unclear if FDA has a recommendation as to if firms should take any action regarding the disposition of food already placed into commerce that was processed on a FCS that had an initial Listeria spp positive and subsequent second FCS Listeria spp positive. Since there is no definitive proof that the product is contaminated with a human pathogen, it is does not seem reasonable to expect firms to recall such products that are already in commerce based on a test result positive for Listeria spp on a FCS.

❖ **EMP Sampling Location:** It is suggested that FDA clarify and specify, that follow-up environmental monitoring sampling that occurs subsequent to an initial sample positive should include re-sampling the same site where the environmental positive was found plus a radius out from the initial sample positive site. The radius sampling would allow the firm to have a better understanding of where L. spp reside in an operation and thus help inform what corrective actions and where corrective actions should be focused. These radius swabs before corrective actions are implemented should not be considered follow-up second swabs as corrective actions have not yet been implemented. It should also be made clear that when different sampling sites test positive for Listeria spp they each count only as an initial sample positive not a second sample positive.

❖ **Quantitative vs Qualitative EMP Testing Results:** It is suggested that FDA provide an opinion as to the use of quantitative versus qualitative environmental monitoring test results, specifically when quantitative results may be helpful for subsequent risk based decision making.
Produce is Unique. It is important to point out that it is possible for fresh produce food contact surfaces to get repeat transient *Listeria spp* positives due to the frequent prevalence of *Listeria spp* on fresh produce. While the use of good agricultural practices and adherence to the FSMA produce safety rule may reduce the introduction of *Listeria spp* during harvest and postharvest handling, farms have few if any known means or controlling or reducing the prevalence of *Listeria spp* on farms where fresh produce is grown.

Records Access: If a firm chooses to speciate *Listeria spp* positive EMP test results to determine whether or not the EMP sample is or is not *Listeria monocytogenes*, must these test results be made available to FDA upon request during a routine inspection? If a firm conducts WGS or PFGE analysis of a *Listeria monocytogenes* EMP sample, must these analyses be made available to FDA inspectors upon request during routine inspection?

Ingredient Testing

*Controlling L. monocytogenes in Raw Materials and Other Ingredients When Contamination With L. monocytogenes Is Reasonably Foreseeable*

3. Controls on suppliers
If you do not use a listeriacidal control measure, we recommend that you establish and implement supply-chain controls designed to reduce the potential that the ingredient or other raw material received from a supplier is contaminated with *L. monocytogenes*. We recommend controls established in collaboration with your suppliers, rather than testing individual lots of raw materials or other ingredients, because limitations on product sampling make product testing a tool that primarily adds value in verifying the adequacy of control measures over time.

We recommend that you establish relationships with suppliers, develop procedures for selecting, evaluating and approving suppliers, and conduct periodic onsite audits to ensure that your suppliers have proper procedures and food safety programs in place and have a serious commitment to food safety. Examples of how to do so include:

- Developing a written supplier approval program based in part on control measures the supplier has implemented for *L. monocytogenes*, using this guidance and relevant regulations as a basis for assessing the control measures to ensure that raw materials and other ingredients are not adulterated under section 402 of the FD&C Act. As part of this program, we recommend that you verify any applicable supplier environmental monitoring program, including results.
- Auditing the supplier’s plant to assess whether the supplier’s raw materials and other ingredients are produced under conditions that are consistent with this guidance.
- Obtaining the raw material or other ingredient under a supplier’s Certificate of Conformance (COC) (guarantee). If you do so, we recommend that:
  - Any COC that you rely on include the period of guarantee, product safety specifications, and a statement that the supplier’s raw materials and other ingredients are produced under conditions that are consistent with this guidance and in compliance with part 117 and
  - You obtain that COC and conduct an onsite audit of the supplier on at least an annual basis.
- Obtaining the ingredient under a supplier’s Certificate of Analysis (COA) (keeping in mind the limitations associated with testing, discussed in section VIII.B.5 of this guidance) indicating that the raw material or other ingredient meets the written product safety specifications. We recommend that any COA that you rely on include the sampling plan and the analytical results.
of testing to detect Listeria spp. or L. monocytogenes, including the analytical method used and limits of the analytical method. See section XVII for our recommendations regarding analytical methods to detect Listeria spp. or L. monocytogenes.

4. Testing when receiving raw materials and other ingredients under a COC or COA
If your controls on raw materials or other ingredients include a COC for L. monocytogenes, we recommend that you periodically test raw materials and other ingredients received under the COC to verify the efficacy of the supplier’s control programs. The frequency of your periodic testing should be sufficient to maintain confidence that the supplier’s control programs are effective and could be reduced if the results of your audits and verification tests demonstrate compliance with your specifications and the supplier’s COC.

If your controls on raw materials and other ingredients include a supplier’s COA that includes test results for L. monocytogenes, we recommend that you verify the results of the supplier’s COA on multiple lots of raw materials and other ingredients you receive until you have enough experience with that supplier to be confident in the results provided on the COA. After you have established confidence in your supplier, we recommend that you continue to test raw materials and other ingredients that you receive under a COA on a periodic basis (e.g., weekly, monthly, or quarterly based on risk) to verify the efficacy of the supplier’s control programs for L. monocytogenes. We recommend that you establish and follow written procedures for any sampling and testing of raw materials and other ingredients, including your sampling plan and procedures for collecting samples, preparing samples for analysis, and your analytical methods for testing samples for L. monocytogenes. See section XVII of this guidance for our recommendations for such procedures.

5. Testing as the only control on raw materials or other ingredients
We emphasize that testing a single lot of a food product for L. monocytogenes is of limited value in establishing the acceptability of that lot and cannot substitute for appropriate controls on its manufacture/processing. The primary value of product testing is as part of a history of test results that is used to verify the adequacy of control measures over time. We also emphasize that testing an incoming ingredient does not provide the same level of assurance as developing a supplier approval program based, in part, on the control measures the supplier has implemented for L. monocytogenes and your periodic verification that the supplier is implementing appropriate controls for L. monocytogenes.

However, if you choose to test an incoming ingredient for the presence of Listeria spp. or L. monocytogenes rather than establishing controls on your supplier (such as some or all of the controls recommended in section VIII.B.3 of this guidance), we recommend that you test incoming raw materials and other ingredients on a periodic basis (e.g., weekly, monthly, or quarterly) commensurate with your supplier’s demonstrated ability to minimize the presence of L. monocytogenes based on your prior test results on raw materials and other ingredients provided by your supplier (keeping in mind the limitations associated with testing). Such testing should be more frequent if your final product is not formulated to prevent the growth of L. monocytogenes.

You should have a process in place to segregate and hold all raw materials and other ingredients that are tested prior to use and products that will be affected by test results.

C. Records
We recommend that you establish and maintain the following records regarding your raw materials and other ingredients:

- Your list of raw materials and other ingredients for which contamination with L. monocytogenes is reasonably foreseeable;
• Any written supplier program that you develop;
• Documentation of the results of any audit of a supplier;
• Any Certificate of Analysis or Certificate of Conformance (i.e., supplier’s guarantee) that you rely on to control L. monocytogenes in raw materials or other ingredients;
• Your written procedures for sampling and testing raw materials and other ingredients, including your sampling plan and procedures for collecting samples, preparing samples for analysis, and your analytical methods for testing samples for L. monocytogenes;
• The results of any tests to detect L. monocytogenes in a raw material or other ingredient.

(Excerpted from DRAFT Lm Guidance Page 51)

Comments:

• **Preventive vs Reactive Approaches:** PMA concurs with FDA’s assertion that lot by lot acceptance testing is of limited value and that supplier controls are the most effective means of assuring ingredients have a low probability of being contaminated with Lm. We also agree that that assuring produce supplier adherence to Good Agricultural Practices, the FSMA Produce Safety Rule and specifically to preventive controls that address the risk of food contact surface-to-produce cross contamination, are the most effective means of reducing the risk of *Listeria monocytogenes* on fresh produce due to harvest and postharvest handling. However, as pointed out above, produce growers have few if any means of reducing the prevalence *Listeria monocytogenes* in produce fields or orchards. Therefore, routine verification sampling for *Listeria monocytogenes* of fresh produce that is field packed is likely to be a low priority as results may not be actionable. Ingredient testing for *Listeria monocytogenes* is also a redundant approach similar to that of finished product testing for human pathogens. One key issue for produce ingredient testing is that one cannot determine if the food sample positive is due to transient positive for *Listeria monocytogenes* or if the sample positive is due to a resident *Listeria monocytogenes* harborage or niche on a food contact surface.

• **Listeria monocytogenes on non-growth Foods:** *Listeria monocytogenes* in low numbers and low prevalence on a food that will not support the growth of *Listeria monocytogenes* under anticipated storage and distribution conditions, should be considered a low public health risk. This may include some fresh produce raw agricultural commodities that do not support the growth of *Listeria monocytogenes*. As such, FDA should clearly articulate via agency policy that agency resources should not be expended on compliance and enforcement actions associated with situations, where *Listeria monocytogenes* is found in low numbers and low prevalence on raw agricultural commodities. Additionally, it is recommended that FDA articulate in guidance that it is the responsibility of firms engaged in manufacturing/processing to be aware and determine via their hazard analysis when a food ingredient may be transformed from a food that will not support the growth of *Listeria monocytogenes*, to a food that will support the growth of *Listeria monocytogenes* (e.g. fresh apples to caramel apples on stick).

**Finished Product Testing**

*Recommendations regarding an RTE food*

*If you detect L. monocytogenes on an FCS, you should either reprocess with a validated listericidal control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy that lot of RTE food, and consider whether there is product in commerce that should be recalled.*
XIV. Sampling and Testing of RTE Foods

A. Periodic Sampling and Testing of RTE Foods to Verify Adequacy of Your Controls

Periodic sampling and testing of RTE foods that you produce can provide a historical reference of performance for your production plant and verify the adequacy of your control of *L. monocytogenes* over time. We recommend that you test food products for *L. monocytogenes* rather than for *Listeria spp.* because of the risk to public health from *L. monocytogenes* in food. If you choose to test food for *Listeria spp.* and find it to be positive, we recommend you determine whether the *Listeria spp.* is *L. monocytogenes* or treat the food as if it were contaminated with *L. monocytogenes*. We recommend that you hold all product that is represented by the food you test, e.g., food lots produced from cleanup to cleanup.

We recommend that you establish and implement a written procedure for the periodic collection of samples of your RTE food product, and for testing those samples for the presence of *L. monocytogenes*. We recommend that your written procedure include the frequency of sampling (e.g., monthly, quarterly) and the sampling plan. The frequency of sampling and the sampling plan will depend on many things, such as customer requirements, the risk of foodborne illness if the finished product is contaminated with *L. monocytogenes*, and the frequency of detection of *Listeria spp.* in environmental samples.

For recommendations on corrective actions to take if you find *L. monocytogenes* in samples of an RTE food, see section XIV.B of this guidance.

B. Corrective Actions If You Detect *L. monocytogenes* in an RTE Food

If you detect *L. monocytogenes* in an RTE food, we recommend that:

- You reprocess with a validated listericidal control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy the lot(s) of RTE food in which *L. monocytogenes* has been detected. You should consider lots produced between two cleaning and sanitizing cycles to be implicated by the product positive;
- You determine whether other lot(s) of food are potentially contaminated with *L. monocytogenes* and segregate and hold those lots of food. We recommend that you also review environmental monitoring results to determine if other lots could be contaminated. We recommend that you subject potentially contaminated lots to “hold and test” procedures (see our recommendations for “hold and test” procedures in section XIII.F.3 of this guidance). You should reprocess with a validated listericidal control measure, divert, or destroy any lot of RTE food in which *L. monocytogenes* is detected;
- Your corrective actions regarding your plant and your procedures include intensified sampling and testing of FCSs and non-FCSs, followed by the corrective actions we discuss in sections XIII.E and XIII.F of this guidance, until you find the source of contamination and eliminate it; and
- You determine whether food in commerce would be subject to a recall.

(Excerpted from DRAFT Lm Guidance Page 52)
3. “Hold and Test” procedures for RTE food
FSIS has issued guidelines to help establishments that produce certain RTE meat or poultry products to comply with FSIS’ requirements (established in 9 CFR part 430) for the control of L. monocytogenes in those RTE meat and poultry products (Ref. 61) (the FSIS Guidelines). The FSIS guidelines include procedures to hold and test RTE foods for L. monocytogenes. The FSIS guidelines describe ICMSF’s scientifically-based sampling plans that can be used to provide statistical confidence for results of product testing (Ref. 61). The following description is based on the discussion of the ICMSF sampling plans in the FSIS guidelines.
ICMSF categorizes microbial hazards according to risk:
1) Moderate
2) Serious
3) Severe

ICMSF ranks L. monocytogenes as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups e.g., hospital and nursing home patients) (Ref. 62). ICMSF does not identify any circumstances in which L. monocytogenes would be ranked as a moderate hazard.

ICMSF describes 15 different cases of sampling plans (Ref. 62), with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11, and 12 would apply to the serious category of microbial hazards and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to foods intended specifically for highly susceptible individuals (e.g., patients in hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible to foodborne illness; thus, increasing the stringency of the sampling plans is appropriate.

For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of L. monocytogenes will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., L. monocytogenes cannot grow), and for cases 12 and 15, conditions could increase the risk (e.g., foods in which L. monocytogenes can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in Table 5, where n is the number of samples and c=0 means that none of the “n” samples can be positive for L. monocytogenes. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that L. monocytogenes is present at <1 CFU in the sample size.

We recommend analyzing a 25 g sample. If the risk of the population is unknown, we recommend that you use cases 13-15.
Table 5.--Sampling plans for ICMSF cases 10 – 15

<table>
<thead>
<tr>
<th>Conditions Reduce Concern&lt;sup&gt;14&lt;/sup&gt;</th>
<th>Conditions cause no change&lt;sup&gt;15&lt;/sup&gt; in concern</th>
<th>Conditions increase concern&lt;sup&gt;16&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 10</td>
<td>Case 11</td>
<td>Case 12</td>
</tr>
<tr>
<td>n^1=5, c^10=0</td>
<td>n=10, c=0</td>
<td>n=20, c=0</td>
</tr>
<tr>
<td>Mean Concentration</td>
<td>Mean Concentration</td>
<td>Mean Concentration</td>
</tr>
<tr>
<td>1 cfu/32g</td>
<td>1 cfu/83g</td>
<td>1 cfu/185g</td>
</tr>
<tr>
<td>Case 13</td>
<td>Case 14</td>
<td>Case 15</td>
</tr>
<tr>
<td>n=15, c=0</td>
<td>n=30, c=0</td>
<td>n=60, c=0</td>
</tr>
<tr>
<td>Mean Concentration</td>
<td>Mean Concentration</td>
<td>Mean Concentration</td>
</tr>
<tr>
<td>1 cfu/135g</td>
<td>1 cfu/278g</td>
<td>1 cfu/526g</td>
</tr>
</tbody>
</table>

When RTE products are sampled (hold and test), the number of samples (randomly selected) would be as specified for these cases based on the risk of the product and the intended consumers.

The number of samples recommended should be collected in one day and all affected products should be held during the testing period. Testing can be for Listeria spp. or L. monocytogenes. If you obtain any positive results from this follow-up testing (using the ICMSF approach), you should conduct more significant investigations of the cause of the contamination and rigorous corrective actions.

<sup>14</sup> Conditions prior to consumption will result in a decrease of the number of L. monocytogenes (e.g., product will be heated prior to consumption, thereby killing L. monocytogenes).

<sup>15</sup> Conditions prior to consumption are not likely to change the number of L. monocytogenes (i.e., the organism will neither die off nor multiply).

<sup>16</sup> Conditions prior to consumption could result in an increase in the number of L. monocytogenes (i.e., the food will be held under conditions in which L. monocytogenes can multiply).

<sup>17</sup> n is the number of samples to be tested.

<sup>18</sup> c is the number of samples that can be positive.

(Excerpted from DRAFT Lm Guidance Page 48-49)

Comments:

- **Produce Unique Situations**: PMA concurs with FDA’s recommendation that firms “hold all product that is represented by the food you test, e.g., food lots produced from cleanup to cleanup”. However, fresh produce RACs or fresh-cut produce never experience a listeriacidal treatment; therefore, a finished product sample does not provide an indication as to whether or not the positive test result for *Listeria spp* or *Listeria monocytogenes* product contamination is due to food contact surface cross contamination or raw material contamination. Therefore an additional consideration should be given to raw material lots that may need to be placed on hold until sampling/test results are available. Produce raw material lots by their nature can be very large and placing large quantities of raw materials on hold because of finished product testing will be very problematic for the fresh produce industry because of the highly perishable nature of fresh produce and the space required.

- **Coordinated Environmental Monitoring and Finished Product Testing**: It is suggested that FDA consider recommending that firms consider coordinated environmental monitoring and ingredient/finished sampling/testing. Collecting information in this manner may help firms identify likely contributing factors associated with finished product contamination. If finished ingredient and finished product testing are not coordinated with environmental monitoring and finished product sample positive occurs the firm is left to guess as to the likely root cause of finished product contamination (i.e. FCS or raw material lot). Finished product
sampling/testing when done in isolation will not differentiate between transient and resident *Listeria spp* and produce is very prone to transient *Listeria spp*.

- **Finished Product Sampling/Testing Provides Limited Value:** While finished product testing seems to be an intuitive course of action it is in actuality an expensive endeavor, which causes significant loss of perishable product quality and food waste while likely providing actionable information only when a catastrophic failure in preventive controls occurs and the prevalence rate of the analyte is extraordinarily high. Given the complexity of many processing operations with multiple production line and ingredient lots, perishable food product finished product sampling/testing will likely be an expensive endeavor that generates food waste. Finished product testing is an also redundant in that it is verifying that already verified preventive controls are indeed in place and implemented. Last, but not least, finished product testing for human pathogens in finished product is a very reactive approach to food safety and is an unwise use of limited food safety resources with very limited returns.

**Plant Design, Construction and Operation**

We recommend that you separate areas where RTE foods are processed, exposed or stored from areas where raw foods are processed, exposed or stored, and from equipment washing areas, microbiological laboratories, maintenance areas, waste areas, offices, lockers and toilet facilities. (Excerpted from DRAFT Lm Guidance Page 9)

**Comments:**

- **No Listeriacidal Product Treatments for Fresh Produce:** Fresh produce offers unique challenges regarding control of *Listeria monocytogenes* because there are no available listeriacidal kill steps associated with postharvest handling of fresh produce RACs or during fresh-cut produce processing. Because there are no kill steps the concept of zoning is difficult to incorporate into fresh produce RAC handling operations and leaves most operators with simply food contact surfaces and non-food contact surfaces at varying distances from where food is handled.

- **Fresh-cut Produce Processing Zoning:** The concept of zoning is applied in many fresh-cut produce processing operations specifically in areas after washing and drying being designated as high care zones.

- **Produce RAC Zoning:** The concept of zoning is not readily applicable in fresh produce RAC handling operations as produce may be washed but it is almost never placed in hermetically sealed containers or boxes after washing. Additionally, packing house operations for fresh produce RAC packing are often open to the environment where there is little to no distinct high care areas since the packed RACs are in vented boxes or packages, open to the environment, to allow for cold air circulation to keep the produce fresh by removing its heat of respiration.

Not installing trench drains in areas where RTE foods are processed or exposed and, where practical, replacing existing trench drains with enclosed plumbing to a floor drain. Where replacement of existing trench drains is not practical, we recommend that you keep them clean and consider whether equipping them for automatic flushing would be of benefit, taking care to ensure that automatic flushing does not create aerosols that could contaminate product; (Excerpted from DRAFT Lm Guidance Page 11)
Comments:

- **New Construction:** We recommend that FDA consider amending recommendation so that firms should consider not installing trench drains in new food facilities in areas where RTE foods are processed or exposed. In some cases, the use of trench drains may actually be the best option in fresh produce operations to reduce the potential for standing water, especially when large quantities of water are used in such operations to convey fresh produce. Some produce RACs and fresh-cut produce have a propensity to clog normal drains creating insanitary drain backup therefore, the use of trench drains would be most appropriate. Additionally, the recommendation to replace existing trench drains or retrofit existing infrastructure is potentially problematic in that such retrofitting may actually create *Listeria monocytogenes* harborage or niches in the retrofitted floor / drain system. It is very difficult to retrofit flooring surrounding trench drain systems in a manner that will assure both sanitary design and durability. Last, but not least, trench drains in many instances are easier to clean and sanitize with mechanical action than other types of drains.

Clothing

*We recommend that you establish and implement conditions and practices to prevent employee clothing from contributing to the contamination of food with L. monocytogenes. Depending on the type of operation, such conditions and practices include:*

- **Personnel do not wear street clothes in areas where RTE foods are processed or exposed unless the street clothes are adequately covered above the knees (e.g., with a clean smock);**
- **Smocks for personnel in areas where RTE foods are processed or exposed are worn only in the designated RTE area and an adjacent vestibule (i.e., the area where the smock would be put on);**
- **Personnel change into a clean uniform or smock before entering areas where RTE foods are processed or exposed;**
- **Smocks and uniforms are laundered or disposed of daily;**
- **Smocks or uniforms that will be used in areas where RTE foods are processed or exposed are distinguished from those that will be used in other areas (particularly areas where raw foods are processed or exposed) using a mechanism such as color coding; and**
- **Smocks or uniforms are distinguished according to the task that the personnel perform (e.g., production or maintenance). For example, if you restrict the access of maintenance personnel to areas of the plant where finished product is exposed, distinguishing smocks or uniforms by color coding helps to identify the personnel with such restricted access.*

(Excerpted from DRAFT Lm Guidance Page 8)

Comments: PMA has concerns about the recommendations in this section, specifically the clothing requirements for employees whenever an RTE is exposed to the environment.

- **Produce RAC Packing is Purposely Designed to Expose the RAC to the Environment:** Specifically, at issue is that fresh produce RACs often are packed and packaged in a manner that intentionally leaves them exposed to the environment via vent holes in the boxes. These vent holes are intentionally placed in produce boxes to allow cold air to flow through the package and over the fresh produce RAC to remove the produce heat of respiration, maintain product freshness and extend the shelf-life of these highly perishable foods. During distribution and storage in distribution centers many fresh produce RACs are exposed to the environment. It is overly prescriptive and provides little risk reduction to have fork lift drivers and warehouse/distribution employees whom are not directly touching or handling these food products to adhere to the recommendations for clothing outlined in this section of the draft.
guidance. It is simply problematic for such clothing standards to apply any time that a produce RAC is exposed to the environment. It is recommended that FDA consider clarifying that the clothing recommendations put forward in this guidance do not apply to produce RACs during distribution.

- **Produce RACs:** The recommendations put forward in this section of the guidance regarding employee clothing seem overly prescriptive and not commensurate with the risk of contaminating fresh produce RACs with *Listeria monocytogenes*. There are no known produce associated listeriosis outbreaks or produce recalls that have identified employee clothing as likely contributing factor. Hence there is no history of employees clothing being a reasonable source of *Listeria monocytogenes* contamination of fresh produce RACs. Specifically, for produce RACs, it is recommended that FDA consider harmonizing this guidance with 21 CFR 112.32(1) in that employees maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces. This standard of conduct is reasonably likely to prevent food contamination with undesirable microorganisms of public health significance such as *Listeria monocytogenes*.

### D. Controls on Personnel Associated with Specific Areas in the Plant

As noted in section V.A.1, we recommend that you provide separate locker areas, break areas, and cafeteria areas for personnel who handle RTE foods and personnel who handle raw foods, when practical. When doing so is not practical, we recommend that:

- Your environmental monitoring program (see section XIII of this guidance) include monitoring of the travel paths and service areas to show when extra cleaning or a procedural modification is needed;
- You establish a “captive shoe” policy in which footwear for the RTE area is only worn in that area; and

**Comments:** PMA has concerns about the recommendations in this section regarding use of “captive footwear”. Specifically, as there is no listeriacidal treatment associated with fresh produce RTE RAC’s all footwear in a produce packinghouse would need to have a captive footwear policy. This impractical to implement and offers little risk reduction in packinghouse situations, especially if footbaths are routinely employed.

> “Foamers or footbaths (which are wet) generally are more appropriate in a wet processing environment. A dry powdered sanitizer generally is more appropriate in a dry processing environment to keep the environment dry; in dry processing environments, the absence of water prevents the growth of L. monocytogenes.”

(Excerpted from DRAFT Lm Guidance Page 8)

**Comments:** It is unclear as to exactly what FDA is suggesting with regard to the use of a “dry powdered sanitizer” as wet conditions may be needed to activate a dry powdered sanitizer. A dry powdered sanitizer may also serve as a food product adulterant if dust containing the dry powder sanitizer is aerosolized in an enclosed space. It suggested that in dry environments, keeping and leaving the environments dry is probably the most important action that a firm could take to control *Listeria monocytogenes* from establishing itself or creating a niche.
If a drain backs up and water flows into an area where RTE foods are being processed or exposed, we recommend that you take steps to avoid splashing any equipment and follow the sequence of steps described below to clear the drain and clean the area around it:

- Stop any production;
- Remove any uncovered RTE foods from the affected area;
- Clear the drain;
- Clean the affected area with an effective cleaner, then rinse and sanitize; and
- Remove excess water from the floor.

(Excerpted from DRAFT Lm Guidance Page 20)

Comments: It is suggested that FDA consider adding another bullet point to this section: “Prevent/block employee traffic in the affected area”. It also important to note that the last three bullet points need not occur in sequential order as recommended. In some cases, excessive water may need to first be cleared before a drain can be cleared.

Procedures to Collect Samples, Prepare Samples for Analysis, and Test Samples for Listeria spp. or L. monocytogenes

We recommend that you use the following procedures to collect samples, prepare samples for analysis, and test the prepared samples for the presence of Listeria spp. or L. monocytogenes:

- Use the procedures described in Appendix 5 for preparing environmental samples for analysis.
- Use FDA’s “Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples” (Ref. 60) for testing environmental samples.
- Use the procedures described in FDA’s Bacteriological Analytical Manual Online (BAM), Chapter 10 – “Listeria monocytogenes,” “Detection and Enumeration of Listeria monocytogenes in Foods” (Ref. 56) for preparing food samples and testing them for the presence of L. monocytogenes (Excerpted from DRAFT Lm Guidance Page 38)

If you or an outside commercial testing laboratory use an analytical method other than those we recommend in this section, we recommend that the method be a written, scientifically valid method that is at least equivalent to the recommended method in accuracy, precision, and sensitivity for detecting Listeria spp. and L. monocytogenes.

(Excerpted from DRAFT Lm Guidance Page 55)

Comments: The recommendations put forward are extremely prescriptive and set a very high bar requiring that any alternatives be at least equivalent to the recommended method in accuracy, precision, and sensitivity for detecting Listeria spp. and L. monocytogenes. It is suggested the words “at least equivalent” be replaced with “comparable” to provide for use of other new and emerging rapid testing technologies. It is important that the assay be validated for intended use, meaning in some cases for a specific food matrix.

“If you detect L. monocytogenes on an FCS, you should either reprocess with a validated listericidal control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy that lot of RTE food, and consider whether there is product in commerce that should be recalled.”

(Excerpted from DRAFT Lm Guidance Page 51)
Comments: It is suggested that FDA CFSAN or CVM clarify as to what animal species are not susceptible to adverse health consequences by exposure to *Listeria monocytogenes* in human food which has been diverted to animal feed.

**Corrective Actions If You Detect *L. monocytogenes* in an RTE Food**

If you detect *L. monocytogenes* in an RTE food, we recommend that:

- You reprocess with a validated listericidal control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy the lot(s) of RTE food in which *L. monocytogenes* has been detected. You should consider lots produced between two cleaning and sanitizing cycles to be implicated by the product positive;

(Excerpted from DRAFT Lm Guidance Page 52)

Comments: PMA asks for clarification that “lots produced between two cleaning and sanitizing cycles” is essentially all lots produce from clean up to clean up cycles defining a production cycle?

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Figure 2.--- Separation of Raw and RTE Areas by Partitions Put a circle around the differences to highlight (Excerpted from DRAFT Lm Guidance Page 73)

Figure 3.--- Separation of Raw and RTE Areas by Air Flow (Excerpted from DRAFT Lm Guidance Page 74)

Comments: It is suggested that FDA consider highlighting the differences between Figure 2 and Figure 3 as the differences are subtle. This could be done by circling or highlighting the differences between these two figures or listing them in a table. The pop-up box that provides an explanation is very good but this information needs to be made more explicit and easy to find for persons using this guidance.