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**Control of *Listeria monocytogenes* in Ready-to-Eat Foods  
Draft Guidance**

To Whom it May Concern:

United Fresh Produce Association ('United' or 'United Fresh') appreciates the opportunity to provide comment on the draft guidance to industry regarding control of *Listeria monocytogenes* in ready-to-eat (RTE) foods. We commend FDA for drafting guidance to aid in the establishment of effective *Listeria* control programs.

Founded in 1904, the United Fresh Produce Association brings together companies across every segment of the fresh produce supply chain, including growers, shippers, fresh-cut processors, wholesalers, distributors, retailers, foodservice operators, industry suppliers and allied associations. We empower industry leaders to shape sound government policy. We deliver the resources and expertise companies need to succeed in managing complex business and technical issues. We provide the training and development individuals need to advance their careers in produce. Through these endeavors, we unite our industry with a common purpose – to build long-term value for our members and grow produce consumption.

Fresh produce is a raw agricultural commodity (RAC) and much fits within FDA's definition of a ready-to-eat food (RTE). The absence of a kill step necessitates stringent food safety practices throughout the supply chain, from farm to table. This begins with adherence to Good Agricultural Practices (GAPs) (and for most United Fresh members, compliance with the Produce Safety Rule), the cleanliness of harvest equipment and containers, cooling operations, and handling, through the supply chain.

As discussed in more detail in our comments, fresh produce generally grows outside, where *L. monocytogenes* (Lm) is a natural part of the environment. This makes interpretation of ingredient, environmental monitoring and finished product testing results very difficult for fresh produce operators who have no listericidal treatment in their operation. Results from environmental monitoring and finished product testing 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. The low prevalence and load of *Listeria* on produce RACs results from the cumulative application of food safety practices throughout the supply chain. In operations that lack a kill step, such as fresh produce, the goal should be to prevent further introduction or spread of the pathogen using multiple hurdles, and reduce, to the extent practical, the levels of *L. monocytogenes* on

product. Trends in testing can be used as verification of these controls, but need to be part of a comprehensive program.

Our industry recognizes that *Listeria monocytogenes* is a pathogen that needs to be controlled, and in September 2016 United Fresh Produce Association and the Produce Marketing Association established a joint workgroup to address *Listeria* concerns in our industry. In mid-July, we offered a workshop on *Listeria* management to a sold-out crowd and are planning additional workshops.

We appreciate the effort associated with developing a guidance document of this magnitude that has applicability to a broad spectrum of FDA regulated food products. We commend the Agency for providing clear information, using examples, and recognizing that different facilities have different constraints. A workgroup comprised of food safety experts within the United Fresh membership deliberated various aspects of the draft guidance to develop comments on behalf of the association. As the guidance is finalized, United Fresh and our members would be happy to discuss specific issues with FDA to continue the alignment between FDA guidance and industry practice and limitations.

We focus our comments on five main areas, expanded upon below, and offer some additional specific suggestions for the document.

Key areas:

1. FDA should be commended for encouraging a “seek and destroy” environmental monitoring program. FDA should recognize that it will take industry time to adopt these recommendations, from a practical and ideological standpoint, but should encourage consideration of this guidance by any operation assessing the risk of environmental *Listeria*.
2. The guidance should offer different recommendations for products with and without a kill step, so that the focus remains on issues related to harborage rather than transient contamination. While the level of detail and specificity is appreciated, in some situations the recommendations may not be applicable and risk assessment should be used to guide practices for individual facilities and product types.
3. We seek additional guidance on the implication of releasing product after a single positive for *Listeria* spp., if subsequent testing continues to be positive.
4. Research to determine which produce items support or do not support growth is needed, and “growth” needs to be defined.
5. FDA should prioritize their enforcement resources based on public health risk, and should consider, in concert with CDC and others, the need for consumer messaging to communicate risk to sensitive subpopulations, since “zero tolerance” is an aspirational, but unachievable, goal.

To expand upon these points:

1. **FDA should be commended for encouraging a “seek and destroy” environmental monitoring program and focusing on prevention over testing.** FDA should recognize that it will take industry time to adopt these recommendations, from a practical and ideological standpoint, but should encourage consideration of this guidance by any operation assessing the risk of environmental *Listeria*.

This guidance represents a more progressive, risk-based, and public health focused approach to environmental monitoring. It is more closely aligned with the USDA FSIS approach, which has been

credited with encouraging the aggressive testing approach within the RTE meat and poultry industry, which has effectively eliminated *Listeria* outbreaks associated with these products.

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.

The draft guidance is thorough and clearly written, and Table 6 is particularly helpful. The draft guidance provides clear direction for firms just embarking on a *Listeria* control program. Further, FDA's recognition that most species of *Listeria* are not pathogenic is critically important. FDA's clear statements that a positive for *Listeria spp.* does not automatically mean that *L. monocytogenes* is present is scientifically accurate and important to recognize. Given that the FDA-regulated food industry has long been encouraged to assume that a positive test result was indicative of *monocytogenes* unless one could prove otherwise, we expect that it could take some time for industry (including retail and foodservice customers) to adopt and embrace the new approach.

Further, given that portions of the fresh produce industry are still in the process of updating their facilities, equipment and processes to address *Listeria* concerns, we appreciate FDA's suggestions for short and long term preventive measures. We appreciate the level of detailed preventive recommendations offered in the draft guidance and will work with our members to support their short and long term planning. We encourage FDA to educate their investigators on the guidance, and encourage investigators to ask facilities for their strategy around environmental monitoring, rather than expect immediate adoption of all recommendations.

Given that some sections of the guidance appropriately recommend a shift from current industry practice, we suggest that FDA consider emphasizing these sections. For example, on page 45 FDA indicates "Sample and test areas of the equipment exposed by disassembly *prior to cleaning and sanitizing the equipment.*" We believe the latter part of this sentence is critically important and should be emphasized, since it reflects a different approach than what is done within much of the fresh produce industry today. United Fresh is committed to working with our members and others in the produce industry to reinforce the changes that will need to occur in facilities, and in terms of auditor and customer expectations.

The guidance recognizes the limitations of testing and encourages preventive measures. This message may get lost given the emphasis and detail in the guidance associated with testing. United Fresh fully supports progress in the area of hygienic design of both equipment and sanitation. We have worked with Joe Stout and his team at Commercial Food Sanitation to support a hygienic design summit for fresh-cut processors, and expanded the concept at our annual convention in June (for all types of operations, not just fresh-cut). Given the diversity of product types and processes, there is little standardization of equipment in the fresh produce industry, and much of the equipment was installed prior to recognizing the importance of hygienic design. Over the past several years, produce industry

members have prioritized sanitation and made substantial investments in personnel, equipment, and testing, in response to increased industry awareness of risks. Many of our members are planning long term capital expenditures to improve their facilities, but in some cases, easily cleanable equipment has simply not been developed yet. Given the practical considerations offered in the guidance, we expect that FDA investigators will have reasonable expectations (e.g., evaluating how often equipment is broken down and cleaned, reviewing long-term plans) when evaluating a facility's adoption of this guidance.

The rationale behind limiting the application of this guidance to RTE foods regulated under the Preventive Controls Rules is unclear. The Preventive Controls Rule requires that RTE foods with post-process exposure to the environment that will not receive a subsequent treatment be evaluated for the risk of environmental pathogens including *L. monocytogenes*. It's therefore appropriate that this draft guidance was developed with that rule in mind. However, we believe that other sectors of the food industry that are subject to different rules should also be encouraged to consider the recommendations in this guidance, to the extent they apply. Hazards don't recognize regulatory boundaries, and there are other sectors of the food system that should be encouraged to consider the recommendations in this guidance.

- 2. The guidance should offer different recommendations for products with and without a kill step, based on the facility's hazard analysis**, so that the focus remains on issues related to harborage rather than transient contamination. While the level of detail and specificity is appreciated, in some situations the recommendations may not be applicable and risk assessment should be used to guide practices for individual facilities and product types. Specifically, recommendations around supplier control and testing raw materials, zoning in a facility, and finished product testing, should reflect the different interpretation that needs to be applied to fresh produce.

As written, this guidance applies to two types of operations: those that have a kill step, and those that do not. These are very different situations that warrant different approaches to *Listeria* monitoring. Further, the draft guidance applies to facilities that vary widely in the degree of product exposure, from fresh-cut operations, to those that are packing with and without wash steps, to coolers that simply store product. The lack of recognition of the different levels of risk, and different approaches to control, are inconsistent with Preventive Controls rule preamble discussion of the value of testing produce RACs. We believe that, with the adjustments recommended in our subsequent comments around using a risk-based approach, and the development of detailed guidance by the produce industry itself, this guidance document can find broad application.

It appears that the guidance was written with conventionally processed foods in mind. When the manufacturing process includes a kill step, a positive test result associated with a FCS or the product itself can confidently be traced to an issue in the post kill step environment. Fresh produce lacks a kill step. Given the ubiquity of *Listeria* spp. in the natural environment, it is impossible to ascertain if a *Listeria* finding in raw material upon receipt, or a product contact surface, or a finished product, was due to an issue in the facility or in the field. In the preamble to the proposed Produce Safety rule, FDA states "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).” Therefore an investigation into a positive test result (raw material, environmental, or finished product) could be inconclusive in terms of the root cause, making the requirement to take corrective action unreasonable. Although this comment appears in the Produce Safety rule preamble, many registered facilities handle the same fresh, intact produce items and are covered by the Preventive Controls rule (e.g., packinghouses, repackers, distribution centers, etc.).

*Facilities should tie their Listeria control program to their hazard evaluation, and implement measures on the basis of risk.*

FDA should clearly state that the focus of the guidance is on preventing *Listeria* from establishing a niche within a facility. The guidance should recognize that there may be a low prevalence of *Listeria* on products that lack a kill step, and that transient *Listeria* are not a concern, so long as they are addressed so that they do not establish a niche. The objective of a *Listeria* control program in a fresh produce operation should be to prevent harborage and the introduction of additional *L. monocytogenes*. This should be reflected in the facility’s own hazard analysis, which should be used as the basis for the *Listeria* control program.

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, even if they handle RTE products subject to the Preventive Controls Rule. We expect that operations that are washing fresh produce may recognize the need to implement an environmental monitoring program (regardless of which rule they fall under).

The guidance document provides an excellent roadmap for firms seeking to build a *Listeria* control program. Although draft guidance is not enforceable by regulators, it is well respected by the industry and customers and provides a safe harbor, and we therefore request additional flexibility or context in some areas. FDA should encourage the adoption of alternative approaches that achieve comparable public health outcomes.

Facilities that have the technical competency and resources to evaluate risk should be encouraged to do so, rather than conform to a “one size fits all” approach to *Listeria* prevention and testing. For example, a facility in which *Listeria* testing shows low levels of the genus may not need a captive footwear program, whereas a facility which, due to the type and source of product, has a higher level of *Listeria* at receiving may opt to implement such a program in the areas where finished product is handled.

Additionally, while we agree that it is beneficial to provide a sense of the magnitude and scope of an environmental monitoring program, we encourage FDA to acknowledge that a facility’s own risk assessment and environmental monitoring history and trends should be used to determine the appropriate number of samples and frequency with which locations should be tested. Table 3 identifies questions to ask when establishing strategies for environmental monitoring. We believe additional factors should include the results of environmental monitoring within that facility, the sanitary design of the facility, the sanitary design of the equipment, and the resources devoted to cleaning, sanitation, and

maintenance. This approach will help demonstrate how the preventive practices recommended earlier in the document influence the nature of the environmental monitoring program.

We offer the following specific suggestions on how the draft guidance could be adapted to recognize the distinction between a product with a kill step, and products that lack a kill step, like fresh produce, on the basis of risk.

#### *Supplier testing*

Based on the strict definition of “ready to eat”, some fresh produce items would be considered “ready to eat” while still on the farm. Supply chains for fresh produce are varied and complicated, and a recommendation to assume product is contaminated and therefore testing is warranted is misguided when considering fresh produce. Specifically, FDA states on page 23 “In the absence of adequate information about the risk presented by a particular ingredient, we recommend that you handle raw foods, and any other food raw materials and other ingredients that could be contaminated with *L. monocytogenes*, as if they are contaminated with *L. monocytogenes*”.

Section VIII B discusses raw material suppliers. This section seems to be more applicable to the receipt of commercially processed ingredients as opposed to fresh produce. We are not aware of practical steps suppliers can take to reduce the risk of *Listeria* on a farm. We encourage FDA to adapt this section to address the situation faced within the fresh produce industry, or clarify the scope of products that is the target of this section. As later discussed, *L. monocytogenes* is a natural part of the growing environment and we believe that testing at the farm level (the supplier to many registered fresh produce facilities) does not advance FDA’s public health goals, and is in conflict with FDA’s own assessment as stated in the preamble to the Preventive Controls rule (response to comment 525).

For those instances where the supplier’s process should control *Listeria* in the product, we suggest as an example, the request by the customer for periodic Zone 1 pre-op testing by the supplier to determine sanitation effectiveness, after the equipment has been operated for a minimum of 15 minutes. Sanitation post testing could be used to establish a clean break. This would be more effective at determining sanitation effectiveness and potential for product contamination rather than relying on the recommended finished product sampling. This information would then be applied to COA’s. We also do not believe that attempting to verify your raw produce supplier’s environmental monitoring program by testing raw materials is either cost effective or an effective verification activity. As either a negative or positive result does not indicate that a supplier’s food safety programs are effective, this verification of verification is expensive, wasteful, and does not benefit public health. It also causes substantial supply chain disruptions without providing any actionable steps, since produce lacks a kill step and a positive test on a raw material is not necessarily indicative of a problem within the supplier’s operation.

Under the recommendation for finished product testing as an only control, guidance should be provided as to sampling methodology of a COA, such as N=60 sampling, referencing the same statistical sampling that is noted on page 49.

#### *Zoning, “raw” vs. “RTE”, and testing product contact surfaces*

On page 9 of the draft guidance, FDA states “We recommend that you separate areas where RTE foods are processed, exposed or stored from areas where raw foods are processed, exposed or stored.” The draft guidance does not consider circumstances where RTE are raw foods. Since there is no clear

distinction between nRTE and RTE product in fresh produce operations, the draft guidance would benefit from including suggestions on the most appropriate sampling strategies and locations in such scenarios.

United Fresh recommends that the guidance direct fresh produce operations (fresh-cut or packinghouses) to focus their testing programs on areas of greatest risk. FDA recognized the unique nature of environmental monitoring in the fresh produce industry in the preamble to the Preventive Controls Rule. In response 525 FDA states “We do not expect either product testing or environmental monitoring to be common in facilities that process, pack, or hold produce RACs.... 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.”

We agree with FDA that testing, and interpretation of results, does not apply to fresh produce (fresh-cut or RACs) the same way it applies to conventional processing facilities and that resources are best directed at preventing the establishment of the pathogen in produce operations. However, we disagree that testing limitations should preclude the fresh produce industry from taking preventive measures and conducting environmental testing in a risk-based fashion. The draft guidance should encourage operations that handle fresh produce RACs to manage the spread of transient *Listeria* in their facility, and prevent the establishment of growth niches. This is best accomplished by focusing an environmental monitoring program on zones 2 and 3 in order to demonstrate that the transfer of *Listeria* from the earlier to the later parts of the process is adequately controlled (through a multi-hurdle approach including traffic patterns, washing of product, effective cleaning and sanitation processes, etc.). For fresh produce, we believe this approach is more effective than testing zone 1 surfaces during operations.

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. The draft guidance provides, as an example, a program where food contact surfaces are tested weekly, with all food contact surfaces being tested once a month. Further, FDA suggests that samples be equally divided between food contact surfaces and non-food contact surfaces. As stated earlier we believe that the ratio of FSC: non-FCS should not necessarily be 1:1. However, we do appreciate that FDA proposed a quantified starting point for testing, because we recognize that many facilities are looking for clear direction and may not have the technical expertise to establish their own plan. When companies do have that level of technical expertise, we believe they should have the flexibility to adapt a program that fits their situation. We encourage FDA to consider adding a qualifier to the number and frequencies of samples that acknowledges that the program may be more or less intense based on the facility’s own historical data and risk assessment. For example, in section XIII.D.3 we suggest the first sentence be revised to read “*In your written environmental monitoring procedures, the number of sampling sites should be specified based on the risk and nature of food and facility.*” It would be helpful for FDA to identify factors that could be considered that would influence both the number of samples, as well as the ratio between FCS and non-FCS surfaces. 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. The

maintenance and design of the facility and equipment, and the implementation of the preventive measures recommended earlier in the document should also be considered. Recognizing that FDA guidance cannot take all scenarios into account, United Fresh intends to update our existing *Listeria* document to provide specific recommendations to our industry and invites FDA input during this process.

#### *Testing 3 hours into production*

The guidance indicates that a *Listeria* harborage is more likely to be discovered after equipment has been run for several hours than immediately after cleaning and sanitizing (XIII D.4. and throughout). This is logical although we are not aware of published studies that demonstrate the rate of finding *Listeria* after 30 minutes, 1 hour, 2 hour, etc. and recommend that a facility should determine the appropriate time to test based on their own internal studies, which presumably will be equipment-specific. Nevertheless we agree that testing immediately after sanitizing could under-represent a harborage site and that testing should be done under realistic “worst case” conditions. However, we request that FDA clarify that product does not need to be run and that, if it’s possible to run equipment without product, testing under these conditions is acceptable.

As noted previously, unlike most other FDA-regulated food products, fresh produce may carry *Listeria spp.* and running product may result in transfer to the product contact surface. A firm would not be able to differentiate a transient positive (from product or another source) from a harborage or niche. 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 the perceived need to hold product. We recommend that FDA edit the guidance to read (on p. 37) “The most important time to collect environmental samples is after equipment has been operational or immediately after production is complete in instances where production runs are always less than 3 hours, because this allows time for *L. monocytogenes* (if present) to work its way out of harborage sites and contaminate the environment and the processing line (including FCS sites).”

#### *Finished product testing*

FDA recommends that finished product be tested for *L. monocytogenes* (not species) as verification. Environmental monitoring is already a verification activity, and United Fresh feels that verifying verification, considering the nature of fresh produce, is a poor use of resources and is not an effective means to protect public health.

For fresh produce, finished product testing may not be an accurate way to verify an environmental monitoring program because contamination could have occurred in the growing environment.

- Chapin et al. (2014) reported that the prevalence of *Listeria species* was found in approximately 33% of samples obtained from the natural environment (n= 734) and 34% of the time in samples obtained from produce production environment (n=734) in New York State. These data show that *Listeria* species were prevalent in both agricultural and non-agricultural environments.
- Strawn et al., 2013 reported that over 5 weeks when 21 farms in New York State were sampled, Lm was found in 17.5% of produce field soils or drag swab samples (n=263) and 30% of water samples (n=74). (the majority of pathogen positive water samples were from non-irrigation surface water sources).



- Crepet et al. (2007) analyzed the results of over 25,000 samples of unprocessed and minimally processed vegetables and found that approximately 3% were positive for *L. monocytogenes*, albeit at very low levels.
- Recently, Luchansky et al. (2017) published the results of a market basket survey including 1700 samples of cut vegetables and 2400 low acid cut fruit samples, and found a positive rate of 1.12% and 0.5%, respectively.

We recognize that there is zero tolerance for detectable *L. monocytogenes* in RTE foods and feel that additional research is needed to inform industry and regulators about the naturally expected presence, levels, and public health risk of *L. monocytogenes* in various fresh produce items (elaborated upon later in our comments). Given the number of produce servings consumed annually, and the relatively low incidence of listeriosis, it would appear that low levels of transient *L. monocytogenes* do not cause illness in the general population, consistent with the findings of Puillot (2015). This supports our earlier recommendation that FDA encourage industry to focus on preventing *Listeria* from establishing itself in the facility, as opposed to misallocating resources tackling naturally occurring transient *Listeria*. We encourage FDA to allocate its inspectional resources similarly, evaluating a facility for its potential to harbor *Listeria*, rather than focus on test results from which one may draw erroneous conclusions.

If there is a systematic problem, appropriate, aggressive environmental monitoring should detect the issue, and resources are better allocated to this effort as opposed to finished product testing. Because of the statistical likelihood of obtaining a positive result on a product that isn't reflective of a facility/environmental issue, United Fresh suggests that facilities use their environmental monitoring history (focused on zones 2 and 3) as an indicator of issues that may compromise product safety. When such trending signals a problem, rather than testing a food contact surface or product, FDA may consider recommending that the facility stop production and perform a thorough cleaning of the problematic area or equipment and investigation into the reason for the increase in positives. This could also include a review of SSOPs and the body of evidence that supports their effectiveness. We believe this is a more proactive approach.

Further, finished product testing is expensive and wasteful. Because FDA recommends testing for the pathogen itself (as opposed to an indicator), and holding product, this will result in millions of pounds of wasted produce annually, at a time when sustainability and environmental responsibility are highlighted, and the affordability of fresh produce is top of mind, given the health benefits associated with fresh produce consumption. For example, United Fresh members report that when FDA has swabbed their production lines, it resulted in the disposal of an average of 25,000 pounds of fresh produce, with an associated average cost of approximately \$72,000 per swabbing incident (this includes the cost of product disposal, additional sanitation, storage, and labor to fill customer orders).

**3. We seek additional guidance on the implication of releasing product after a single positive for *Listeria spp.*, if subsequent testing continues to be positive.**

Like most of the FDA-regulated food industry, United Fresh supported the FSIS approach to examining FCS for the presence of *Listeria spp.* and advocated for the adoption of this approach by FDA. The previous FDA policy instilled tremendous fear and trepidation around testing FCS. While United Fresh members support the notion offered in the draft guidance that a single positive test result for *Listeria spp.* is unlikely to cause a public health impact, they are concerned that buyers will be more difficult to

convince. The statement that supports this concern appears at the bottom of page 45 “If the food tests positive for *L. monocytogenes*, reprocess, divert to non-food use, send for use in food to be consumed by animals where appropriate, or destroy that product lot and the additional product lots on hold, and **consider whether there is product in commerce that should be recalled.**” (emphasis added).

United Fresh has two concerns related to this statement. First, members of the produce industry are conservative when it comes to food safety and avoid putting product into commerce if there is a chance it may need to be recalled. We recognize that this situation would only occur after aggressive attempts at cleaning the environment, and that for most of the FDA regulated industry, the repeat positives could indicate a persistent problem. However, there is concern that, based on probability, situations would occur in which a series of transients were detected in a fresh produce operation, including a transient *L. monocytogenes* introduced at the farm level, and that these results may lead to an erroneous conclusion of a harborage and therefore trigger a product recall. Conversely, a negative result cannot provide assurance that the food is safe.

Our second concern is that the draft guidance recommends that, should a subsequent positive be discovered upon re-testing, product from that day as well as the next two production days should be held and tested for *L. monocytogenes*. For many United Fresh members, the product shelf life is so short that holding product for 3 days, plus the amount of time it takes to get the last test result, will result in product destruction. When considering the likelihood that many members of the produce industry will hold product during the first FCS sampling, whether on their own or in response to a customer requirement, combined with the chance that transient *Listeria* spp. will be detected, we foresee a tremendous and unnecessary loss of fresh produce as previously discussed. We would like to further discuss this issue with the Agency to determine how the guidance can be adapted to take the unique aspects of fresh produce into consideration and recommend that options such as equipment tear down and swabbing, and review of SSOPs could be more effective approaches.

It is recommended that FDA clearly state that on the days of follow up sampling after a routine zone 1 positive result for *Listeria* spp., the product produced on those days, if deemed able to support the growth of *Listeria*, should be placed on hold until results are available in order to prevent the potential for a product recall, and then reference the location later in the document that refers to this. FDA should also consider recommending that the finished product testing for *L. monocytogenes* can take place at the same time as the follow up swabbing is performed in order to expedite the opportunity for product release should all zone 1 retests come back negative. 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. Further, while finished product testing can be used to provide extra assurance as part of an investigation, it should not be relied upon as a release method.

- 4. Research is needed to determine which produce items support or do not support growth and the reliance of temperature as a control.** Predictive models will support risk-based decision making for fresh-produce items.

FDA appropriately recognizes that corrective actions should be taken based on risk, and that a key consideration is whether the product supports growth of *Listeria*. FDA should indicate what is meant by “growth”, e.g., the logarithmic increase over a set period of time (e.g., the length of time during which

the product is likely to be considered palatable for consumption at ambient or refrigerated temperatures). We recommend that “growth” be defined as a two log increase in microbial population to coincide with FSIS definitions (FSIS *Listeria* Guideline, 2014; [https://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling\\_LM\\_RTE\\_Guideline\\_0912?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling_LM_RTE_Guideline_0912?MOD=AJPERES)). The draft guidance references a one-log increase as related to formulated foods. A one-log difference in counts can be due to analytical variability from inoculation, sampling, and enumeration procedures. To validate using a one-log criterion, an increased number of samples and test events are required to interpret outlying and variable challenge results. For *Listeria* control, as in the FSIS guidance, the risk assessment and higher level of Lm needed to cause illness are considered in the two-log increase challenge criteria. We suggest that FDA state that a “no growth” food is a food that does not support more than a 2-log increase during normal storage and handling conditions.

FDA identifies some foods known to support the growth of *Listeria*, including fresh-cut produce (p. 4 of the draft guidance). However, published studies show that the growth of *Listeria* on fresh-cut produce is product-specific and we request that FDA remove this statement. Data regarding the growth of the *Listeria* on intact produce has been studied to a limited extent. We provide the following examples to illustrate the diversity within the fresh produce category, and to encourage FDA to use the guidance to impress upon readers the need for them to conduct a literature review or consult experts in order to assess the growth potential of the products they handle.

- Flessa et al. (2015) found that “*L. monocytogenes* is capable of survival but not growth on the surface of fresh intact *or cut* strawberries throughout the expected shelf life of the fresh fruit....” Their work showed a 3 log reduction of the pathogen inoculated on intact berries when held at 4°C for 7 days. Populations on cut surfaces remained constant, even when held at 24°C.
- Salazar et al. (2016) found that “*L. monocytogenes* inoculated at the stem end and the equatorial surface survived but did not grow on fresh Gala and Granny Smith apples stored at 25°C for 49 days.” This study reviewed many other variables that demonstrate that multiple factors need to be considered when assessing growth potential.
- Farber *et al.* (1998) found that fresh-cut shredded carrots do not support the growth of *L. monocytogenes*
- Nyarko et al. (2016) evaluated the growth of *L. monocytogenes* on fresh cut cantaloupe under refrigeration and storage conditions. The product supported growth (3 log increase after 15 days at 4°C or after 7 days at 10°C).
  - In a separate publication, this research team showed that populations of *L. monocytogenes* decreased by at least 2 logs on the rind of cantaloupes after 7 days of storage between 4-25°C. However, the pathogen did grow at the stem scar when held at 25°C, but not under refrigerated conditions.
- Bolten and colleagues have shown that *L. monocytogenes* does not grow in cabbage, onion, broccoli or pineapple juices (<https://iafp.confex.com/iafp/2017/webprogram/Paper15486.html>).
- Beuchat and Brackett (1991) studied the survival of *L. monocytogenes* on raw tomatoes and in chopped tomato products. The pathogen grew on intact tomatoes held at 21, but not 10°C, and counts decreased on chopped tomatoes held at either temperature.

On page 27 (X A1), FDA references pH 4.4 as a no-growth boundary. Many fresh produce items have an internal pH of less than 4.4., but are not formulated products. Additionally, the surface (rind, peel, skin) may have a very low water activity, while the inside of the fruit or vegetable may have a high water activity. It is not clear how this information can be used by operations that handle intact produce. If the product will be transformed (including being cut or pierced), facilities should assess the potential for growth of *L. monocytogenes*, and this should be included as part of their hazard analysis as required by the Preventive Controls Rule.

The comment toward the top of page 32, in section XI, that “RTE foods be stored at 4°C (~40°F) or below” is not appropriate for fresh produce items, particularly those that are RACs. In our comments on the draft guidance for the Preventive Controls for Human Food Rule, we stated “The produce industry recognizes that fresh produce RACs ... are considered RTE products. The vast majority of these products grow in environments that exceed 70°F. The refrigeration parameters in the draft guidance could be interpreted to mean that bananas, avocados, whole tomatoes, and other items commonly stored at ambient temperature would need to be refrigerated.”

In the fresh produce industry, including fresh-cut, temperature control generally stems from quality, not safety, concerns. The draft guidance references the model Food Code, which limits the amount of time specific products (fresh-cut leafy greens, sliced tomatoes, sprouts, and cut melons) can exceed refrigeration temperatures. The *Listeria* guidance should similarly provide a recommendation on *time* not just temperature. Otherwise, product held at 42°F for one minute could be deemed to be against the recommendation in the guidance document. The time-temperature combinations that yield a “significant” (to be defined; United Fresh suggests 2 logs over the anticipated shelf life under ordinary handling and storage condition)) increase in the growth of *L. monocytogenes* are expected to be product-specific. Most fresh produce has a short shelf life. Slow microbial growth (in the rare instances where *L. monocytogenes* is present) has a lesser impact on public health than situations where rapid and prolific growth occur. The produce industry would benefit from the establishment of predictive models and encourages FDA to conduct or support research that can populate these models, and hopes the agency will harness the expertise of its risk assessors and modelers to develop such a tool.

5. **FDA should prioritize their enforcement resources based on public health risk**, and should consider, in concert with CDC and others, the need for consumer messaging to communicate risk since “zero tolerance” is aspirational, but not achievable.

*Listeria monocytogenes* in low numbers and low prevalence on a food that will not support the growth of the organism 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 *L. 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 *L. monocytogenes* is found in low numbers and low prevalence on produce raw agricultural commodities.

As noted previously, despite the best efforts of the produce industry, *L. monocytogenes* can be isolated from fresh produce items at low frequency and generally at low levels (loads). The public health relevance of low level contamination from the growing environment, and virulence of isolated strains, is not currently known. Mere presence should not be misconstrued as a major public health risk because most intact fresh produce does not support the growth of the pathogen, and to date, outbreaks

associated with fresh produce have been linked to conditions with a facility, not on the farm. We do not believe that sporadic, low level contamination in the growing environment ordinarily renders the product injurious to health.

Relative to other parts of the food system, in which finished product should be free from *L. monocytogenes* post processing, individual test results in fresh produce facilities cannot conclusively direct an operation to meaningful corrective actions. Therefore we recommend that the Agency limit its inspectional focus on testing in fresh produce operations (and products) and instead deploy trained investigators to critically evaluate the facility-specific and handling-specific factors that may contribute to *Listeria* harborage, growth, and transfer. United Fresh and allied produce associations will be delivering training and will work with our members to help them identify short and long term changes that need to be made to improve their *Listeria* management plans within their facilities.

FDA has stated that the peer-reviewed publication “*Listeria monocytogenes* dose response revisited--incorporating adjustments for variability in strain virulence and host susceptibility” by Pouillot et al. (2015) has guided FDA policy regarding *L. monocytogenes* specifically FDA's position that the absence of a zero regulatory action limit for *L. monocytogenes* would result in 50 deaths/year. The paper states that “the exposure data we used in deriving the dose-response model did not consider bacterial growth from retail to consumption.” The potential for temperature abuse and mishandling during this part of the supply chain should not be overlooked. The omission of potential growth (in products that support growth) diminishes the effect of FDA’s important distinction in the draft guidance between foods that do and do not support the growth of *Listeria*. The paper therefore predicts that foods that don’t support pathogen growth are associated with illness to a much greater extent than exists in actuality. The authors considered a maximum level of contamination of 6.1 log cfu/g, which corresponds to the maximum level of *L. monocytogenes* isolated from a market basket survey (Luchansky et al., 2017). Again, the market basket survey does not include growth that may occur between the point of purchase and point of consumption. The paper acknowledges that allowing this parameter to rise from 6.1 to 8.1 cfu/g, produced a corresponding change in the “average concentration in contaminated products of 20,545 cfu/g as compared to 390 cfu/g for the baseline scenario.” This has the effect of attributing more illnesses to lower ingested doses.

Despite the fact that the Puoillot paper used extremely conservative assumptions that over-attribute illness to very low doses of *L. monocytogenes*, United Fresh recognizes that a subset of consumers is at substantially increased risk of listeriosis. We encourage FDA to work with other public health agencies to consider providing healthcare providers and the sensitive subpopulation with appropriate recommendations.

**6. In addition to these overarching comments, we also offer some specific recommendations for consideration:**

- FDA should replace the term disinfectant with “EPA- registered sanitizer.”
- On p. 7, the last paragraph of section IV A discusses the recommendation that footwear worn in nRTE areas not be used in RTE areas. For many fresh produce facilities, there is no such thing as an nRTE section; produce may be transported directly from a farm, and meets the RTE definition at the point of harvest. Another example is produce in a warehouse. It is common for fresh produce to be stored in vented packaging or containers, which technically makes it “exposed to the environment.” However, FDA, in the preamble to the Preventive Controls rule, properly notes that most hazard analyses would deem the risk of environmental contamination to be

low. In such case, we do not feel that a captive footwear program (recommended as the last bullet on p. 8) is warranted, and the inconsistency between the draft guidance and the rule preamble as related to RTE produce RACs should be addressed.

- Section IV A on p 7 does not take into account the use of foamers, footbaths, and shoe covers, addressed in section IV B of the draft guidance (p 7). We recommend that FDA reverse the order of information presented in the second paragraph in IV A so that the paragraph begins with the first sentence “We recognize that contact between hands and food...”
- p. 7, section, IV B, discusses foamers, footbaths and dry powdered sanitizers. We recommend adding this information to the previous section where footwear is discussed. We encourage FDA to consider that the spread of *Listeria* through a facility via footwear can be managed either through a captive footwear program or footbaths, foamers, dry powdered sanitizers, or a combination. A facility’s environment monitoring program can help support such decisions.
- p. 8. The recommendations put forward 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 employee 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*.
- p. 11. The recommendation related to filtered air has limited applicability in some produce operations, particularly packinghouses, which may be open air facilities. Facilities with more controlled environments still lack a kill step, such that filtering air is unlikely to be as protective as other measures. United Fresh members recognize that air should not be a source of contamination, but request that FDA modify this recommendation to reflect that the value of filtering air should be assessed by each facility.
- p. 11. 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 fresh produce operations the use of trench drains may actually be the best option 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 *L. monocytogenes* harborages 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. Finally, in many instances trench drains are easier to clean and sanitize with mechanical action than other types of drains, however, regardless of drain style, it is imperative that drains be designed and maintained in a cleanable condition.
- p. 12. We also recommend editing the language around pallets. “Clean” is a subjective term. We suggest that instead of FDA recommending that pallets be “clean”, the Agency recommend that

pallets be inspected prior to use, and that the facility establish criteria to determine when a pallet is appropriate for use.

- p 14, last paragraph: Include height of conveyors above floors: i.e., many companies use elevator conveyors that circle back to being only inches from exposed floors and foot traffic. Some type of recommendation for “splash height” or enclosure of this area is suggested.
- p 15, VI B, FDA should consider adding the need for sanitation verification (swabs) for washed tools before use in a RTE environment
- p 17. ATP tests should be performed at step 5, before sanitizer is applied, to allow recleaning (if necessary) before sanitizer is used.
- p 30. FDA recommends intensified sampling in some instances, but does not use the term “vector swabbing” or the concept of sampling in a multi-dimensional radius. 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 *Listeria* spp. reside in an operation and thus help inform what and where corrective actions should occur. Radius swabs on non-FCS that are taken before corrective actions (e.g., enhanced sanitation) 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.
- p 44 under section of corrective actions: The definition of a “lot” of product notes one days production on a processing line, with cleaning and sanitizing between production lots. We recommend that this be defined as a “clean break” for the record. “Clean up to clean up” can take place at any time within the production period, such as within 1 hour, 15 minutes, 4 hours, or 24 hours.
  - On page 45, the example discusses production days. While this is an example, it may be more useful for FDA to reword this section around production “cycles” since a cycle may not equal one day.
  - On page 49, Sample collection, FDA should clarify the number of samples taken should be from 1 lot, and not from 1 day as indicated. This will keep the terminology the same, if the Agency clarifies that a lot is identified as from clean up to clean up, not one day’s production.
- FDA should consider adding a recommendation that, after the initial 3 intensified cleaning and swabbings are complete, the location of the original *Listeria* spp. positive be placed on an intensified rotation schedule for a minimum of 4 weeks in a row prior to being placed back onto routine sampling. This will help ensure that, under normal production and sanitation procedures, the location remains clean and free of niches and harborage sites.
- p. 56. FDA recommends that a “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*.” We suggest that FDA replace the word “equivalent” with “comparable.” We believe this more closely aligns with FDA’s recommendations earlier in the document that the method be scientifically valid (which is consistent with the use of “scientifically valid” test methods in the Preventive Controls rule).

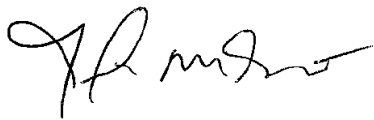
## Closing Comments

Finally, we recognize that this draft guidance is related to forthcoming guidance on RTE foods. We request that the FDA consider re-opening the comment period when all related guidance documents are available for public review.

United Fresh members developed an industry guidance document on *Listeria monocytogenes* in 2013 and intends to update this document to reflect and expand upon FDA's draft guidance. We invite FDA to be a part of this process. We recognize that fresh produce has unique considerations relative to *L. monocytogenes* and will support FDA's approach by tailoring industry guidance to address these specific issues. Guidance, including draft guidance, provides safe harbors for industry and direction to investigators. While we overwhelmingly support the direction FDA has taken in this draft compared to the 2008 version, we have some concerns over the application to fresh produce and hope that FDA will quickly finalize this guidance with our comments in mind so that the produce industry is not held to an unattainable standard.

We have also worked with the Produce Marketing Association to develop a member-driven workshop on the control of *Listeria* modeled after the RTE meat industry program. We appreciate FDA's participation in this workshop and look forward to continued collaboration in order to effect progress in the fresh produce industry. Again, we appreciate the opportunity to offer input, and would be pleased to meet with the Agency to discuss any of our comments.

Sincerely,



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