

***LISTERIA* REGULATIONS IN THE FDA AND USDA:
IMPLICATIONS FOR DUAL-JURISDICTION FACILITIES**

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TABLE OF CONTENTS

Introduction	- 1 -
I. Background	- 1 -
A. Public Health Significance of <i>L. monocytogenes</i>	- 2 -
B. History of Regulation – USDA	- 3 -
C. History of Regulation – FDA	- 4 -
II. Current Regulations and Policies	- 5 -
A. USDA Regulations – 9 CFR § 430.....	- 5 -
B. FDA Regulations – 21 U.S.C. § 342, 21 C.F.R. § 110	- 6 -
C. Compliance Policy Guides	- 7 -
III. Agency-Specific Requirements	- 8 -
A. Food Contact Surface Testing.....	- 8 -
B. Non-Food Contact Surfaces.....	- 11 -
C. Corrective Actions for Positive <i>Listeria</i> Findings	- 11 -
D. Other Agency Differences.....	- 13 -
Conclusion	- 14 -

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INTRODUCTION

The federal government regulates the safe production of food through both the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA). All meat and poultry products (and certain egg products) are under the supervision and inspection of the Food Safety and Inspection Service (FSIS) branch of the USDA, while other food products come under the jurisdiction of the FDA. Some food manufacturers make both USDA and FDA regulated items, thus becoming what is termed a dual-jurisdiction facility. Companies in that situation are required to follow both USDA and FDA issued laws and policies. The USDA and FDA have different regulations and viewpoints on the control of *Listeria monocytogenes* (*L. monocytogenes*), making compliance with the various policies and meeting the requirements of each agency complex at times. This paper will review the reasons behind the importance of *L. monocytogenes* control and the current regulatory policies in effect for both the USDA and FDA, and suggest how to most effectively comply with both agencies' requirements.

I. BACKGROUND

Understanding *L. monocytogenes* and the history of its regulation are crucial to appreciate the risks and critical nature of its control in a food manufacturing setting.

A. Public Health Significance of *L. monocytogenes*

L. monocytogenes is a pathogenic bacterium that is ubiquitous in the environment and has been isolated from water, soil, humans, domestic animals as well as food processing environments¹. It is known to be a foodborne illness² that when found in contaminated food can cause serious illness and potentially death. The people most at risk for listeriosis are the young, elderly, immune-compromised and pregnant women (at risk for miscarriage or stillbirth)³. Despite its low prevalence compared to other foodborne pathogens⁴, it is taken very seriously by federal regulators responsible for food safety due to its very high incidence of hospitalizations (up to 90% of all infections) and fatalities (as many as 20% of all infections)⁵.

L. monocytogenes is unusual in that it can grow under refrigeration and survive in freezing environments⁶, whereas most other pathogenic bacteria do not grow and multiply at temperatures below 40°F. This is a major concern for manufacturers who rely on refrigeration as a defense against foodborne pathogens. It is also very tolerant of

¹ Fenlon, DR. 1999. *Listeria monocytogenes* in the natural environment. *Listeria, Listeriosis and Food Safety*. Ryser E.T. and E.H. Marth, eds. Food Science and Technology, New York: Marcel Dekker Inc., 21-37.

² Ryser, E. 1999. Foodborne Listeriosis. *Listeria, Listeriosis and Food Safety*. Ryser E.T. and E.H. Marth, eds. Food Science and Technology, New York: Marcel Dekker Inc., 299-358.

³ Slutsker, L. and A. Schuchat. 1999. Listeriosis in humans. *Listeria, Listeriosis and Food Safety*. Ryser E.T. and E.H. Marth, eds. Food Science and Technology, New York: Marcel Dekker Inc., 75-95.

⁴ FDA and FSIS, USDA. 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. <http://www.foodsafety.gov/~dms/lmr2-toc.html>. (Last accessed 12/2/08.)

⁵ Gellin, B.G., and C.V. Broome. 1989. Listeriosis. *J.A.M.A.* 261:1313-1320.

⁶ USDA. 2006. Compliance Guidelines to Control *Listeria Monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products. http://www.fsis.usda.gov/oppde/rdad/FRPubs/97-013F/LM_Rule_Compliance_Guidelines_May_2006.pdf. (Last accessed 12/2/08.)

heat and high salinity, and forms biofilms on equipment, making control measures difficult⁷. While *L. monocytogenes* infection occurs only sporadically, outbreaks have been linked to failures in processing environments, such as the recent incident that occurred in sliced deli meat from Maple Leaf Foods in Ontario, Canada. As of October 17th, 2008, that outbreak alone caused 20 deaths and 53 confirmed cases of listeriosis, with more cases still under investigation.⁸

B. History of Regulation – USDA

The Food Safety and Inspection Service (FSIS) has the authority to regulate all meat and poultry producers under the Federal Meat Inspection Act (FMIA)⁹ and the Poultry Products Inspection Act (PPIA)¹⁰. In 1987, the USDA initiated testing for *L. monocytogenes* in Ready-To-Eat (RTE) meat and poultry products, and established a “zero tolerance” policy (no detectable level of viable organisms allowed). In 1996, FSIS issued the “Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; final rule” which established mandatory Sanitation Standard Operating Procedures (SSOPs) and Hazard Analysis and Critical Control Points (HACCP) systems for all meat and poultry processors¹¹. This regulation also required the establishment of monitoring and pathogen reduction programs for micro-organisms to be established by

⁷ Lou, Y. and A. Yousef. Characteristics of *Listeria monocytogenes* Important to Food Processors. *Listeria, Listeriosis and Food Safety*. Ryser E.T. and E.H. Marth, eds. Food Science and Technology, New York: Marcel Dekker Inc., 131-224.

⁸ Public Health Agency of Canada. Oct. 17, 2008. *Listeria monocytogenes* outbreak. http://www.phac-aspc.gc.ca/alert-alerte/Listeria/Listeria_2008-eng.php (last accessed on 11/27/08.)

⁹ Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.)

¹⁰ Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.).

¹¹ USDA. July 25, 1996. Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; final rule. (61 FR 38806). Available online at:

each facility.

In May 1999, FSIS issued directive 10240.2 instructing all meat and poultry processors to reassess their HACCP plan to consider the potential hazard of *L. monocytogenes* contamination in ready-to-eat (RTE) foods. The directive instructed processors that “If reassessment results in a determination that *L. monocytogenes* contamination is a food safety hazard reasonably likely to occur in the production process, then it ... must be addressed in a HACCP plan”¹². It suggested processors look at pathogen levels in raw materials, validation of lethality treatments, post-lethality exposure and history of product contamination as factors in conducting risk assessments of their products.

On June 6, 2003, FSIS published an interim final rule that amended its regulations to require that official establishments that produce RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *L. monocytogenes*. Under USDA jurisdiction, control of *L. monocytogenes* is required under 9 CFR § 430¹³.

C. History of Regulation – FDA

The FDA, along with the USDA, has been monitoring the prevalence of *L. monocytogenes* in the food chain for many years. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) provided strategies to minimize the incidence of *L. monocytogenes* in food in 1991.¹⁴ The food industry was not required to

<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf> (Last accessed on 12/2/08.)

¹² FSIS, USDA. May 1999. *Listeria* Guidelines for Industry.

<http://www.fsis.usda.gov/oa/topics/lmguid.htm> (Last accessed on 12/2/08.)

¹³ 9 C.F.R. § 430.

¹⁴ National Advisory Committee on Microbiological Criteria for Foods (NACMCF). 1991. *Listeria*

adopt those strategies by regulation, and despite progress in reducing the incidence of listeriosis by 50% over the next several years, further declines were not achieved. In 1999, the FDA collaborated with the USDA to fund a research effort to assess the public health risk of *L. monocytogenes*.

In a Presidential Address in May, 2000, President Clinton announced a goal to reduce listeriosis by 50 percent with a target rate of 0.25 cases per 100000 by 2010, but preferably by 2005¹⁵. In response to that target, the USDA and FDA collaborated and published the draft risk assessment of *L. monocytogenes* in select categories of RTE foods in early 2001, and the final version in September 2003¹⁶. The risk assessment was designed to evaluate the effectiveness of various programs and interventions on *L. monocytogenes* control in the highest risk categories of foods, and provide the agencies with tools to reduce the incidence of listeriosis and limit its public health impact.

II. CURRENT REGULATIONS AND POLICIES

The public health significance of *L. monocytogenes* and potential public harm as result of a listeriosis outbreak gave rise to rule-making and legislation from the agencies responsible for maintaining the safety of the U.S. food supply.

A. USDA Regulations – 9 CFR § 430¹⁷

The USDA regulation with respect to the control of *L. monocytogenes* is very

monocytogenes: Recommendations by the National Advisory Committee on Microbiological Criteria for Foods. *International Journal of Food Microbiology* 14:185-246.

¹⁵ FSIS, USDA. May 2000. Revised Action Plan for Control of *Listeria monocytogenes* for the Prevention of Foodborne Listeriosis. [http://www.fsis.usda.gov/OA/topics/Listeria monocytogenes_action.htm](http://www.fsis.usda.gov/OA/topics/Listeria_monocytogenes_action.htm) (Last accessed 10/26/08.)

¹⁶ FDA and FSIS, USDA. 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. <http://www.foodsafety.gov/~dms/lmr2-toc.html>. (Last accessed 12/2/08.)

short and has only two sections. 9 CFR § 430.1 defines the terms used. 9 CFR § 430.4(a) states that *L. monocytogenes* is a hazard that an establishment producing RTE product that is exposed to the post-lethality environment must control. A company may do so either through its HACCP plan or it may choose to prevent potential contamination in the processing environment through the use of Sanitation Standard Operating Procedures (SSOPs) or other prerequisite programs. The regulation also states that RTE product is adulterated if it contains *L. monocytogenes*, or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. This clause gives the USDA grounds for legal action against a company whose products or production lines have positive test results. 9 CFR § 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are permitted to choose from in order to meet the requirements of 9 CFR § 430.4(a). 9 CFR § 430.4(c) outlines the validation and verification options and requirements associated with selecting the Alternative a plant will follow. 9 CFR § 430.4(d) and (e) request submission to FSIS (USDA) of an annual estimate of RTE production, and permit the use of claims regarding treatment of a product with a lethality treatment or anti-microbial agent, respectively.

B. FDA Regulations – 21 U.S.C. § 342, 21 C.F.R. § 110

To date the FDA has not issued specific regulations on the control of *L. monocytogenes* in FDA-regulated facilities. The agency does, however, have control over products contaminated with that pathogen. 21 U.S.C. § 342 classifies a food as adulterated “If it bears or contains any poisonous or deleterious substance which may

¹⁷ 9 C.F.R. § 430.

render it injurious to health.¹⁸ *L. monocytogenes* infection and listeriosis resulting from the consumption of food containing that organism can cause severe illness and harm. 21 CFR § 110 is the FDA's Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.¹⁹ This regulation, while not specific to *L. monocytogenes* control measures, is the regulatory basis for FDA activity with respect to pathogenic bacteria. It requires that food be produced, stored and held such that it will not become adulterated. Contamination of a food product with *L. monocytogenes* is considered adulteration by the FDA²⁰ and the agency's position on the subject has been upheld by the courts.²¹

C. Compliance Policy Guides

Both the FDA and USDA have issued Compliance Policy Guides for industry with respect to the appropriate measures that should be taken by food manufacturers to control and prevent contamination of food with *L. monocytogenes*. In the case of the USDA, the Guide explains the regulation (9 C.F.R. § 430) and how it expects processors to implement control measures, including criteria to consider in the creation and implementation of programs, and how to comply with the regulation itself.²²

The FDA recently issued a draft Compliance Policy Guidance document for

¹⁸ 21 U.S.C. § 342.

¹⁹ 21 C.F.R. § 110. Available

²⁰ FDA. Draft Compliance Policy Guide. Sec. 555.320. *Listeria monocytogenes*. http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/draft_cpg555-320.html (Last accessed 12/4/08.)

²¹ United States of America v Union Cheese Company, Pages 778-792, 902 Federal Supplement, United States District Court, N. D. Ohio, Eastern Division.

²² USDA, 2006. Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products. <http://www.fsis.usda.gov/oppde/rdad/FRPubs/97->

manufacturers regarding *L. monocytogenes* in February, 2008.²³ This policy guide is in addition to the requirements of 21 CFR § 110 outlined in the current Good Manufacturing Practices (cGMPs). Similar to the USDA Policy guide, it outlines controls that processors should establish and implement to control the incidence of *L. monocytogenes* in their products. Despite not containing any binding regulations, the document specifies that “processors may choose to use other control measures to comply with the requirements in 21 CFR part 100, as long as they provide an equivalent level of assurance of safety for the product”²⁴. The effect of this sentence is to ensure that processors are either following the policy guide, or have reasonable evidence to support an alternative decision and process for control of *L. monocytogenes*.

III. AGENCY-SPECIFIC REQUIREMENTS

Despite having a common goal of reducing the incidence of listeriosis outbreaks and limiting the impact of *L. monocytogenes* contamination on the public, the two federal food agencies have different methods to accomplish that objective.

A. Food Contact Surface Testing

Under the USDA regulation (9 C.F.R. § 430), there are three choices of processes to control potential *L. monocytogenes* contamination, called Alternatives one, two and three. Two of the three alternatives require testing for either *L. monocytogenes* or an equivalent indicator organism such as *Listeria* species. Alternative one is intended for products that have both a post-exposure lethality step and an anti-microbial treatment

[013F/LM Rule Compliance Guidelines May 2006.pdf](#). (Last accessed 12/4/08.)

²³ FDA. 2008. Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods. www.cfsan.fda.gov/~dms/Listeria_monocytogenesrtegui.html (Last accessed on 10/21/08.)

that has been shown to either reduce or inhibit the growth of *L. monocytogenes* over time. The facility must validate and verify the effectiveness of both the post-exposure lethality step and the anti-microbial aid or process. The USDA does not require the use of an environmental *L. monocytogenes* sampling program for products that meet those criteria, however they recommend companies sample food contact surfaces at least twice a year.

Alternative two regulations mandate testing for products that have either a post-exposure lethality treatment OR an anti-microbial treatment. This alternative requires the testing of two food contact surfaces at least every quarter on every production line where RTE products are manufactured. Again, the testing may be for either *L. monocytogenes* or an indicator organism.

Alternative three regulations require product contact surface testing at minimum on one food contact surface per month, up to a total of four per month, per line, depending on the size of the facility and the type of product being made. Hot dogs and deli-style meats have been shown to have a higher risk of *L. monocytogenes* contamination²⁵, and therefore come under closer scrutiny. Processors of those items are required to have increased testing according to the regulation.

In comparison, a sampling program is only recommended for the control of *L. monocytogenes* under FDA regulations. In their Compliance Policy Guide, a single level of sampling is suggested for all food contact surfaces, with a frequency of once a week,

²⁴ *Id.* Section IV.

²⁵ U.S. Food and Drug Administration and US Food Safety and Inspection Service. 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. <http://www.foodsafety.gov/~dms/lmr2-toc.html>. (Last accessed 12/2/08.)

and a minimum of five sites per line. The actual number of tested sites should be determined based on plant size and product risk according to the Guide, but with the above mentioned minimums²⁶. In addition, it recommends that ALL critical food contact sites (those areas of equipment or facility which will or are likely to come into contact with food where the product might become contaminated) be tested at least once a month.

This is a significant difference in policy from the USDA standards and the FDA's stance is considerably more aggressive. For example, a plant with two production lines making RTE non-hot dog, non-deli meat products (i.e. chicken salad) with an antimicrobial process (under Alternative two) that also makes a comparable non-USDA item (i.e. tuna salad) on those same lines should test at least five sites on each line every month, according to the FDA. Under the USDA standards, they are required only to test two sites per line every quarter.

	USDA	FDA
Alternative 1 Post-exposure lethality treatment AND anti-microbial agent.	2 food contact sites / line / 6 months (Voluntary.)	5 food contact sites / line / week. Test all identified FCS / month. No differentiation between product type/category. (Voluntary.)
Alternative 2 Post-exposure lethality treatment OR anti-microbial agent.	2 food contact sites / line / quarter (Mandatory.)	
Alternative 3 (Sanitation only to control <i>L. monocytogenes</i> .)	1-4 food contact sites / line / month, depending on product and size of operation. (Mandatory.)	

²⁶ FDA. Center for Food Safety and Applied Nutrition. Feb. 2008. Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods. Draft Guidance. (http://www.cfsan.fda.gov/~dms/Listeria_monocytogenesrtegui.html) (Last accessed

Assuming an average cost of \$25/test, for a manufacturer under USDA Alternative two with two production lines, the difference is \$100/quarter under the USDA guidelines and \$1500/quarter under FDA guidelines. If said processor makes both USDA and FDA regulated products, they are held to different standards by both agencies.

B. Non-Food Contact Surfaces

In addition to testing food contact surfaces, the FDA compliance guidelines recommend testing environmental areas for *L. monocytogenes* or an indicator organism like *Listeria* species at a minimum of five sites every two weeks, with the goal of testing all identified sites within a quarter. The USDA does not require environmental *L. monocytogenes* testing nor does it recommend a frequency for doing so. It is, however, encouraged and expected, particularly in response to finding positive test results on a food contact surface. Both agencies recommend taking corrective actions upon discovering the presence of either *L. monocytogenes* or *Listeria* species.

C. Corrective Actions for Positive Listeria Findings

Another area the USDA and FDA differ in with respect to *L. monocytogenes* control is their corrective action requirements after identifying a positive test result on a food contact surface. Any product manufactured on a production line that has tested positive for *L. monocytogenes* since the time of the last sanitation period or negative test result could be expected to be carrying some amount of the bacteria through transfer from the equipment to the food and is thus likely contaminated, and would be considered adulterated.²⁷ Shipping food products from processing areas that are

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²⁷ USDA. 2006. Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products.

undergoing pathogen testing is risky and unwise in the event of a positive result, which would result in a recall.

The USDA differentiates its corrective actions between Alternatives one, two and three. For Alternative one and Alternative two products that include a post-exposure lethality treatment, a positive food contact surface result for *L. monocytogenes* or *Listeria* species does not necessarily mean the product is adulterated. Both of those alternatives assume the facility has documented evidence supporting the efficacy of the lethality treatment, and that the product has been rendered safe to consume.

For products which have only an anti-microbial process (Alternative two) or that rely solely on sanitation of the facility to prevent contamination (Alternative three), any food produced in contact with a surface testing positive for *L. monocytogenes* is considered adulterated and assumed to be contaminated. Under this scenario the product in question must be held and tested (and recalled, if it entered distribution), and if the test results are positive, either destroyed or reworked with a validated listericidal process.

The FDA differentiates its response to positive results for food contact surface testing based on whether or not the product supports or does not support the growth of *L. monocytogenes*. Foods with one of the following criteria: a pH of less than 4.4, frozen, or water activity of less than 0.92, do not provide an opportunity for growth. Also, the presence of anti-microbial hurdles (such as lactic acids, sorbates, diacetates, etc.) can reduce the viability of microorganisms, particularly *L. monocytogenes* and

foods formulated with those types of hurdles may also be included in this category.²⁸

For foods which do not support *Listeria* growth, the FDA recommends holding and testing all products manufactured on a line where a food contact surface test result is positive for *L. monocytogenes* or *Listeria* species. For any finished products with a positive test result the action taken varies depending on the level of bacteria in the sample. The FDA proposes that as long as the product has <100 cfu/g *L. monocytogenes* and the food does not support its growth, it is safe to ship that product. For samples testing >100 cfu/g, the FDA suggests treating the product with a listericidal control measure, diverting the food to animals (as long as it is not adulterated for animals), diverting the food to a use in which it is not consumed and destroying the food if necessary.

For products which do support the growth of *L. monocytogenes*, the FDA recommends holding and testing all products manufactured on a line where the food-contact surface test was positive. If the testing reveals the product is contaminated, they recommend treating the food with a listericidal control measure, reprocessing the food so that it is undetectable for *L. monocytogenes*, diverting it for another use or destroying it.

D. Other Differences

One area in which the USDA and FDA have drawn different conclusions is the amount of *L. monocytogenes* that can be present in food products before causing illness. FSIS and the USDA issued a response to the FDA Draft Guidance for Industry regarding

²⁸ FDA. Center for Food Safety and Applied Nutrition. Feb. 2008. Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods. Draft Guidance. (http://www.cfsan.fda.gov/~dms/Listeria_monocytogenesrtegui.html) (Last accessed

proposed permissible *Listeria* levels in various food products. Specifically FSIS was strongly critical of FDA's recommendation to set an upper limit of 100cfu/g as acceptable for certain RTE products.²⁹ In their opinion, there is insufficient scientific data to support an upper limit of 100 cfu/g as being "safe". Additionally, some strains of *L. monocytogenes* are more virulent than others and there is a concern that while most healthy people would not be affected by lower amounts of *L. monocytogenes*, some would and the risk to public health and safety could be increased by the higher allowance of viable organisms. In addition, the FDA draft guidance document does not address the possibility or control of cross-contamination between a product that does not support growth (but contains detectable *L. monocytogenes* up to 100cfu/g) and one that supports growth and is produced in the same area, or on the same production line where it may have been contaminated.

CONCLUSION

Control of *L. monocytogenes* is crucial to maintaining public confidence in the food supply as well as reducing the incidence of foodborne illness caused by it. Since the FDA has not promulgated a regulation requiring *L. monocytogenes* sampling to date, for the moment facilities under dual-jurisdiction are only legally required to meet the USDA requirements. The current FDA policy guidelines for *Listeria* are considerably more stringent than those of the USDA. If the FDA were to create binding regulations, it would be hoped that they would be in alignment with the measures required by the USDA since the goal for both agencies is the same; to prevent listeriosis outbreaks.

12/04/08.)

²⁹ FSIS Office of Public Health Science and the Office of Policy and Program Development. Re: Docket No. FDA-2008-D-0058. Pg. 13-14

Because the FDA allows a processor to justify alternate sampling and control measures in their facility than those suggested in their policy guide, a processor could use solely the USDA regulations as an adequate program for *L. monocytogenes* control at this point in time.

It is generally accepted that the more comprehensive a management program followed by a food processor, the better the control they have over *L. monocytogenes*. A major portion of both policy guidelines from the federal agencies involves the testing of food contact surfaces for the presence of either *L. monocytogenes* or indicator organisms such as *Listeria* species. One of the challenges of this testing is the necessity to hold all products manufactured on those production lines until test results are received. The extensive FDA recommendations could be a considerable financial burden for a food company not only with respect to the cost of testing, but the effect of testing and holding short shelf-life products can affect the ability of a company to meet its customer's needs.

Environmental (non-food contact) sampling allows a company to monitor the sanitation of the processing plant without incurring the expense and complexity of holding products. While not required by the USDA, a prudent company will invest in sampling for *L. monocytogenes* or indicator organisms using an environmental testing program. The determination of the amount and frequency of testing should be determined on a plant-by-plant basis and included as a control measure for all facilities interested in controlling *L. monocytogenes*.

Regardless of jurisdiction, the prevention of foodborne illness is beneficial for consumers and businesses alike. The USDA regulations do not include mandatory environmental testing, which would improve *Listeria* control, whereas the FDA policies

as written could create a significant financial burden for food processors. An intermediate approach that includes incorporating hurdles into product formulation and the use of food-contact and environmental sampling plans designed for specific processing facilities will produce the desired goal: reduction in the incidence of foodborne listeriosis.