



June 23, 2015,

MEMORANDUM FOR INSPECTION ADVISORY COMMITTEE AND SCIENTIFIC AFFAIRS COMMITTEE

FROM: SCOTT GOLTRY

SUBJECT: CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT MEAT AND POULTRY PRODUCTS

The Food Safety and Inspection Service (FSIS or the agency) last week [issued an affirmation of the June 2003 interim rule addressing Control of *Listeria monocytogenes* \(*Lm*\) in Ready-to-Eat Meat \(RTE\) and Poultry Products](#). On October 6, 2003, the agency supplemented the interim final rule with the "FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products", which was updated in January 2014. The affirmation of the interim rule states, "Based on available data, FSIS is confident that it is successfully carrying out its mission to protect public health by enforcing safeguards designed to control *Lm*. The Agency considers the RTE regulatory results to be an excellent indicator of the trends in pathogen presence in RTE products over several years. This downward trend shows that the interim final rule has been effective in controlling *Lm* in RTE meat and poultry products."¹ Because this affirmation of the interim rule provides minor conforming amendments and imposes no new or substantive requirements, FSIS determined that notice and comment rulemaking on the changes is unnecessary. However, FSIS will accept comments through August 18, 2015. The rule becomes effective September 17, 2015.

Summary and Regulation Changes

FSIS asserted the interim final rule led some establishments to question whether they may perform further confirmation testing after a positive finding of *Listeria monocytogenes* (*Lm*) in an RTE product and then release the product into commerce. FSIS removed provisions concerning additional establishment testing in response to *Lm* results in 9 CFR 430.4(b)(2)(iii)(B), (b)(3)(i)(B), and (b)(3)(ii)(B). As revised, the regulations refer only to additional establishment testing in response to positive indicator organism results. In addition, FSIS removed provisions that suggest that establishments may "be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes*" from 9 CFR

¹Docket No: FSIS-2014-0033, Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry, 80 *Fed. Reg.* 35178 (June 19, 2015)

30.4(b)(3)(ii)(C), because, as 9 CFR 430.4(a) provides, such product is adulterated and cannot be released into commerce. FSIS also removed the requirement that establishments report production volume and related information to FSIS because this information is collected through PHIS.

9 CFR PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

430.4 Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. 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*. Establishments must not release into commerce product that contains *L. monocytogenes* or that has been in contact with a food contact surface contaminated with *L. monocytogenes* without first reworking the product using a process that is destructive of *L. monocytogenes*.

(b) * * *

(2) * * *

(iii) * * *

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

* * * * *

(3) * * *

(i) * * *

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for an indicator organism;

* * * * *

(ii) * * *

(B) During this follow-up testing, if the establishment obtains a second positive test for an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) In order to release into commerce product held under this section, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

I hope this information is helpful. If you have questions please contact [me](#).
Thank you.

cc: Barry Carpenter
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