AMERICAN MEAT INSTITUTE

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2710

FSIS Docket Clerk
Food Safety and Inspection Service
United States Department of Agriculture
Room 102 Cotton Annex Building
300 12th Street SW
Washington D.C. 20250-3700

97-013P-2710
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RE: FSIS Docket No. 97-013P: *Performance Standards for the Production of Processed Meat and Poultry Products*

To whom it may concern:

The American Meat Institute (AMI) is the national organization representing the interests of meat and poultry slaughterers and processors and their suppliers throughout North America. AMI's members produce the majority of meat and poultry products manufactured in the United States. We appreciate the opportunity to comment on the above-referenced docket (the proposal).

Subsequent to publication of the proposal AMI and the National Food Processor's Association (NFPA) surveyed their respective member companies in August 2001 to learn more about industry practices and how the proposed rule might alter them (hereinafter the survey). Seventy-five surveys representing 75 companies and 170 plants were returned (see Attachment 1). Respondent answers were broken down by plant size, using the Small Business Administration size standards, large, small, and very small. In

addition, a fourth category, "combination," represents companies with both large and small plants.

AMI supports promulgating regulations that enhance and encourage the production of safe and wholesome meat and poultry products. Responsible public food safety policy is developed by establishing regulatory goals that are tied to measurable human health outcomes and achievable standards for the production and distribution of meat and poultry products. To achieve these goals it is imperative that industry and government, here the Food Safety and Inspection Service (FSIS or the agency), work together.

AMI and its members have carefully reviewed the proposed rule and have identified a number of significant problems with it. In that regard, the proposal would impose substantial new requirements on industry without providing any concomitant benefit to public health. Indeed, for example, the proposed *Listeria* testing regimen could actually discourage companies from designing the most effective testing program possible. The several problems articulated throughout these comments, coupled with the fact that the proposal would impose significant costs with no benefit to the public health, compels AMI to oppose, in large part, the proposed rule.

Significantly, even a cursory review of the economic information leads to the conclusion that this proposal qualifies as a major rule from an economic impact standpoint. Indeed, just one large meat and poultry processor has conservatively estimated compliance costs to be approximately $30 million. Simply aggregating the costs likely to be incurred by the four or five largest processors easily exceeds the $100 million threshold.

AMI's comments regarding the proposed rule are divided into six sections: Lethality; Stabilization; *Listeria monocytogenes;* Thermally Processed Commercially Sterile Products; Draft Guidelines; and Economic Impact. The first four sections discuss the proposal and AMI's substantive concerns, followed by a discussion of the draft guidelines and the proposal's economic impact.

For the reasons set forth in the discussion below, the agency should withdraw the proposed rule and, if appropriate, publish a new proposal that factors in the substance of these and other comments received.

I. Lethality

1. Proposed Changes

The proposal provides two options for meeting the lethality standard, either a confusing statistical probability of survival of a target organism or a specified reduction of a target organism. However, the proposal states that any detectable levels of viable pathogens or their toxins throughout the product's shelf-life would render ready-to-eat (RTE) products adulterated. This language and the concepts underlying it are confusing.

The agency should clarify the standard to read "following the lethality step in the process, any products with detectable viable reference pathogens (*i.e. Listeria monocytogenes*), would render the product adulterated." This is the standard for RTE products. If the agency chooses to provide additional information regarding statistical probabilities, determination of hypothetical worst case, and specified reductions it could be done through guidance material.

This approach would provide establishments with flexibility in meeting the performance standards, while providing the agency an opportunity to update the guidance materials with current information without repeatedly having to go through the notice and comment rulemaking process.

2. E. coli O157:H7 *in Fermented Products*

The proposal includes a provision for an additional lethality performance standard for fermented RTE products that include any amount of beef, except thermally processed, commercially sterile products. The proposal would require establishments either to meet a specific probability of surviving cells of *E. coli* O157:H7 (*E. coli*) in 100 g of a sample of product made from worst case scenario raw materials, or establishments may employ processes validated to achieve a 5.0-$\log_{10}$ reduction of *E. coli* throughout the fermented product. The presence of *E. coli* in a RTE fermented meat product, however, renders that product adulterated.

After the 1994 illnesses caused by *E. coli* in RTE fermented sausages, FSIS, industry, and researchers participated in a Blue Ribbon Task Force, which led to the development of several options for processing fermented products to achieve a 5-log reduction of *E. coli* O157:H7. This effort is an excellent example of cooperation between the industry and FSIS to solve a previously unrecognized food safety issue. The Task Force's coordination and cooperation yielded guidelines that have been widely adopted by the fermented meat sector of the industry. The five options from the Blue Ribbon Task Force are described in detail in the proposal and since 1995 when the validated processing options were implemented, there have been no documented cases of *E. coli* illness associated with fermented meat products. The cooperative nature of the development and implementation of these science based processing options has been, and will continue to be, the best way to solve challenging food safety problems.

Against this background, establishing lethality performance standards for *E. coli* in fermented products is unnecessary because the agency and industry have properly addressed this food safety issue. The information provided in the proposed rule regarding the five processing options, the statistical probabilities, determination of hypothetical worst case scenario estimation can be provided through guidance material for those establishments that wish to use it. This approach would provide establishments with flexibility in meeting the performance standards, *i.e.* no detectable *E. coli* in fermented sausages, while providing the agency an opportunity to update the materials with current information without having to go through the notice and comment rulemaking process.

II. Stabilization

1. Proposed Changes

The proposed rule would require that RTE products be stabilized to ensure no growth of *Clostridium botulinum* (*C. botulinum*) and no more than 1-$\log_{10}$ multiplication *of Clostridium perfringens (C. perfringens).*

2. *Concerns*

The proposed standards are designed to reduce the chance of *C. perfringens* and *C. botulinum* toxin from reaching levels known to cause human illness.

C. perfringens and *C. botulinum* are spore-forming bacterium. The vegetative cells are destroyed during the lethality treatment, although the spores may not be. Outgrowth of *C. perfringens and C. botulinum* from spores can occur if the product is held at ideal temperatures for growth for extended periods of time.

According to the Centers for Disease Control's (CDC) "Surveillance for Foodborne-Disease Outbreaks-United States, 1988-1992," there have been no outbreaks associated with *C. botulinum* or *C. perfringens* in commercially prepared meat and poultry products. Based on the report, the outbreaks that occurred were associated with raw meat and poultry products and uncooked product that were subsequently held for extended periods of time.[1]

A. Clostridium perfringens

Based on data collected in the FSIS microbiological surveys, the agency assumed starting levels of *C. perfringens* spores of 10^4 g in meat and poultry products. This assumption is not based on available scientific data. The FSIS microbiological survey data was based on vegetative cells, not spores. In addition, industry has found that there is a loss of viability of vegetative cells, rather than an outgrowth, during refrigeration.

AMI supports the suggestion that the stabilization performance standard for *C. perfringens* apply only to the surface of intact, whole muscle, RTE products. There is no evidence or reason to believe that *C. perfringens* would be found in the interior of any intact muscle cut. Given that *C. perfringens* is not a blood-borne pathogen, it is not reasonable to assume that it would be found in the interior of any intact muscle cut.

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[1] On September 3, 2001, 15,000 pounds of frozen chili products thought to contain *C. botulinum* toxin was recalled. However, to date, the product has not been implicated as containing the toxin, nor has the point of abuse been established.

B. *Clostridium botulinum*

FSIS has asked whether the *C. botulinum* standard should be no (zero) multiplication as proposed, or whether there is sufficient data to support a possible relative growth tolerance in place of the no growth standard. Through this question FSIS recognizes: 1) it is possible to have a small amount of *C. botulinum* growth without affecting product safety; 2) that demonstrating "no multiplication" by experiment is difficult and can be extremely expensive; and 3) that there is a lack of mathematical modeling data available to develop predictive growth models for cell population growth.[2] Considering the uncertainty that currently exists, FSIS should wait to establish a performance standard for *C. botulinum* until the agency has gathered more information on the relationship of the spore population to toxin production and public health.

Although stabilizing products is important for safety, it is equally important for quality control. Hardier spoilage organisms that survive cooking must be controlled or the product will spoil. Therefore, there is an incentive to stabilize products properly without having a required performance standard for *C. perfringens and C. botulinum.*

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[2] AMI is aware that USDA's Agricultural Research Service is in the process of evaluating a beta version of the new Pathogen Modeling Program (PMP 6.0), which, among other things, includes dynamic temperature models for cooling for *C. botulinum* and *C. perfringens.* These models are currently under review.

2. Relevant Industry Findings

According to the industry survey, C. *perfringens* spore levels in raw meat and poultry have been found at the following levels:

***C. perfringens* spores/g**				
Product	**Number of samples**	**<3**	**3-100**	**>100**
Ground turkey	154	154	0	0
Ground pork	11	9	2	0
Ground beef	6	6	0	0
Pork sausage	26	26	0	0
Total	**197**	**195**	**2**	**0**

In addition, one company tests raw batters containing combinations of beef, pork, and poultry. That company's data indicates that the majority of positive samples contain between 10 to 40 *C. perfringens* spores per gram. Furthermore, AMI is aware of a member company that tested 50 products that had cooling deviations. Of 50 products tested, only two had detectable levels of spores, both of which were well below the level necessary to cause illness.

AMI recommends that FSIS evaluate the impact of RTE products on public health. The agency should determine if implementing the proposed regulations will have a dramatic impact on public health prior to imposing them on industry. In addition, the agency should conduct true baseline studies to determine the level of spores in raw meat and poultry products. Until these two activities are completed, FSIS should not finalize this portion of the proposal. Upon completion of the baseline studies, FSIS should set a standard that allows companies the necessary flexibility to meet such a standard. **III. *Listeria monocytogenes***

1. Proposed Changes

The proposal would require manufacturers of RTE products to test the environment for *Listeria spp.* at specified frequencies, based on the number of plant employees. In addition, the proposal would require that establishments test product if the product passed over a product contact surface that tested positive. This procedure would effectively require establishments to hold product while monitoring the environment for *Listeria* or *Listeria* like species. Such a requirement, if implemented, would be extremely problematic, logistically and economically, to the affected industry.

2. Concerns

Preliminary data released by CDC in April 2001 indicate that the incidence of listeriosis was lower in 2000 than in previous years. Specifically, the Foodborne Diseases Active Surveillance Network (FoodNet) indicates that the incidence of listeriosis per 100,000 people has dropped from 0.6 in 1998 to 0.4 in 2000. These preliminary data indicate that industry is well on its way to meeting the goal of reducing listeriosis by one half by the year 2005, in line with the President's initiative.[3] Such data raise legitimate questions as to whether more regulatory changes are needed to achieve that objective. This concern is especially appropriate given that producers of ready-to-eat meat and poultry products are currently required to meet a performance standard for *Listeria monocytogenes* – a standard of zero.

The agency's proposal to require environmental testing for *Listeria* is unnecessary and reminiscent of the old command and control inspection system. The underlying principle of the Hazard Analysis and Critical Control Point (HACCP) system is prevention. The agency moved to the HACCP system to eliminate the prescriptive industry requirements that existed under the old system of meat and poultry inspection. Under HACCP, the agency should be setting reasonable, measurable, science-based performance standards that will benefit public health. The agency should not dictate the way in which the industry meets the performance standard. Yet, requiring environmental testing and dictating testing frequency, based solely on the number of employees at a facility, is neither science-based nor

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[3] "Preliminary FoodNet Data on the Incidence of Foodborne Illnesses" --- Selected Sites, United States, 2000
http:www.cdc.gov/mmwr/preview/mmwrhtml/mm5013a1.htm.

tied to public health. Indeed, it is exactly the type of command and control mindset the agency professes to avoid.

The agency arguably moved in the right direction when it published Directive 10,240.2 Revision 1 (the Directive), issued December 1, 2000, and titled "Microbiological Monitoring Program: Sampling, Testing Procedures and Actions For *Listeria monocytogenes* and *Salmonella.*" The Directive states that RTE product must be free *of Listeria monocytogenes* and *Salmonella,* but does not prescribe how a plant must meet the standard.

That Directive, as originally written in 1998, outlined procedures for, among other things, inclusion of all pathogens and microbial toxins and cleanup-to-cleanup lot definition. It did not recognize, however, the sporadic, environmental nature of some pathogens. The revised version became effective on December 1, 2000. The revisions included realigning the testing programs into HACCP categories, eligibility for establishments conducting their own testing for reduced agency sampling, and follow-up agency sampling protocol.

Under the Directive, establishments may randomly test one product per HACCP plan per month or randomly test one product per HACCP plan every three months, coupled with ongoing product contact and non-product contact surface testing. Such testing must be included in an establishment's HACCP plan or SSOPs. Moreover, testing protocols, results, scientific justification for frequency, sampling methods, randomness, *etc.*, must all be made available to inspection personnel. Considering that the revised Directive was issued in December 2000, a mere two months before the proposed rule was published, it seems unreasonable for FSIS to attempt to impose a new rule without allowing companies to implement the options in the Directive – especially in light of the recent evidence of a downtrend in listeriosis since the development of the original directive and its subsequent revision. In short, the agency could not have had enough time to review the effectiveness of that directive's implementation before developing the new proposed regulation, which may be completely unnecessary.

Consistent with HACCP principles, the agency should set a performance standard and let industry achieve that standard. FSIS should allow companies the flexibility to monitor their systems in ways that provide

companies with the most information about the effectiveness of their processes. The prescriptive nature of this proposed rule is a stark contrast to that philosophy and prohibits companies from using plant-specific programs to control *Listeria*. Moreover, the agency should review the effect that Directive 10,240.2 Revision 1 has had on food safety prior to developing any new and possibly unnecessary regulations.

A. Testing frequency

Controlling *Listeria* in the processing environment is key to ensuring that safe, RTE meat and poultry products reach consumers. Environmental (product contact and non-contact) testing is but one aspect of a *Listeria* control system. AMI supports using *Listeria* control programs in establishments manufacturing RTE products. Sanitary design of facilities and equipment provide the system's foundation, while sanitation practices, in combination with product and employee flow, provide the system's operating structure. A well designed testing regimen will assist a manufacturer in determining whether the system's design and operation are sufficient to protect the integrity of the product or if change is needed. Data analysis and corrective actions are equally important, as they assist the manufacturer in controlling the environment.

HACCP systems are different across facilities and each establishment requires its own approach. Yet, the agency has offered a cookie cutter approach to testing by proposing that:

- large plants conduct at least four tests, per line, per month;
- small plants conduct at least two tests, per line, per month;
- and very small plants conduct at least one test, per line, per month.

Establishment age, plant layout, location, number of lines, employee retention rate, current level of control, *etc.*, all play a role in determining how a testing regimen should be designed. Basing the amount and frequency of testing solely on the number of individuals employed at an establishment is insufficient to determine the amount of testing that should be done.

Indeed, the agency admits that the proposed testing frequency is arbitrary because the preamble provides that "FSIS has not been able to correlate risk of product contamination with production volume or

establishment size." 66 *Fed Reg.* 12603 (Feb. 27, 2001) That is, the agency has "picked" a testing frequency out of convenience rather than science. In the absence of any scientifically based correlation, it is inappropriate for FSIS to assign testing frequencies in what is, at best, an arbitrary manner.

The agency attempts to justify the proposed frequency assignment by saying "[H]owever, assuming that large establishments produce a greater volume of product than do small establishments, and that a large unsanitary establishment would be more likely to contaminate more product and thus pose more risk to the public health, FSIS is proposing to require large plants to test more often." *Id.* This assumption is erroneous. According to the agency's own economic burden estimates, "almost 60 percent of all the establishments that could be potentially affected by the proposed rule are classified as small," *Id.* at 12612, indicating that small facilities produce a significant volume of ready-to-eat products.[4]

That an establishment is classified as "large" and employs more individuals than an establishment classified as "small" does not directly translate into larger production volume of RTE products. Many large establishments produce a variety of products, not all of which are classified as ready-to-eat. Therefore, a "small" plant, which may have 498 employees for example, could produce more ready-to-eat product than a "large" plant. In addition, a processing line can move the same amount of product, regardless of whether it is located in a large plant or a small plant. Thus, the risk of adulterated product on a line is not a function of the number of employees, but the various science-based factors previously mentioned.

Basing testing frequency on number of employees alone is neither scientific nor a reasonable basis for designing a testing program meant to protect public health. The agency should rescind this portion of the proposal.

3. Industry Practices

According to the survey, 47 of 75 respondents are utilizing one of two options and 24 are not using either option, while four respondents claimed

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[4] Not insignificant is the fact that a large plant may have 510 employees and a small plant may have 498 employees and the small plant may produce notably more RTE product – highlighting the very arbitrary and ineffective manner in which FSIS has proposed its testing program.

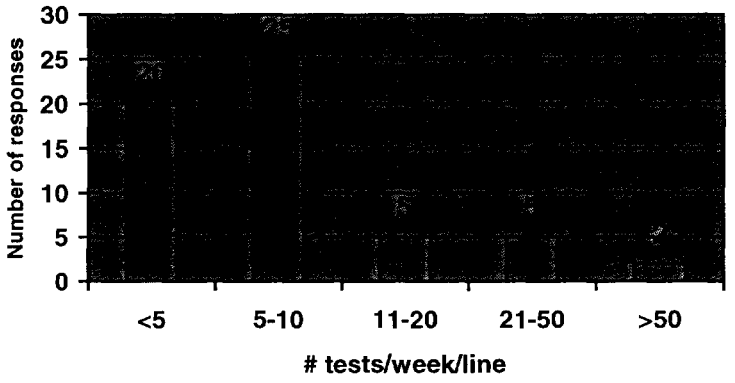
the options listed in the Directive were not applicable. According to respondents, 66 percent are utilizing option one, conducting monthly product testing. Fourteen companies are utilizing option two, conducting quarterly product testing coupled with product contact and non-contact surface testing (or 30 percent). Two companies indicated that they are utilizing options one and two in combination.

Twenty-four companies indicated they were not utilizing either of the two options. Of those companies, 20 claimed that they were doing some testing to verify control of *Listeria*. A majority (12) of the 20 respondents are conducting product testing, coupled with product contact surface and non-product contact surface testing. However, their testing scheme does not fit the options as described in Directive 10,240.2.

Of respondents sampling for *Listeria*, the majority (39 and 40 respectively) test for *Listeria spp* on product contact surfaces and non-contact surfaces. The survey indicates, on average, large plants are taking approximately 17 samples, small plants are taking approximately six to seven samples, combination plants are taking seven to eight samples, and very small plants average one to two samples across one line, per week, on product contact surfaces. Please see Chart 1 below, for a breakdown of number of tests run per line.

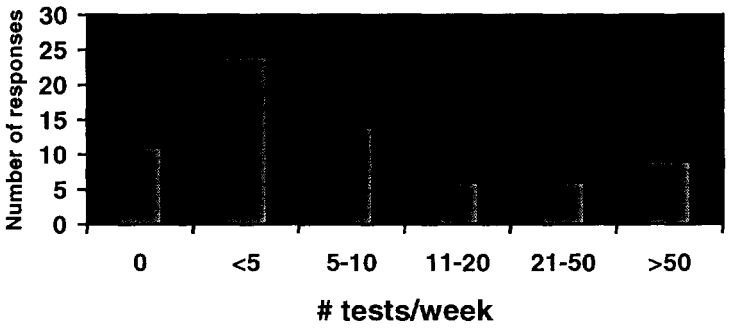
On average, large companies are taking 47 samples, small companies

Chart 1. Product Contact Surface Tests



are taking 11 samples, combination companies are taking 66 samples, and very small companies are taking between one and two samples per week, across lines, on non-contact surface areas. Please see Chart 2 below, for a breakdown of the number of tests run per week on non-contact surface areas.

Chart 2. Non-Product Contact Surface Tests



The majority of companies choose not to composite product contact samples, nor do they composite non-product contact samples. However, very few plants classified as very small responded to this survey question. Because very small plants tend to have smaller budgets, they likely will

composite samples for cost saving purposes. When asked which testing methodology plants were utilizing to test for *Listeria*, answers varied, with the ELISA, AOAC, BAX, USDA, and Vidas tests mentioned most frequently.

Given the number of questions raised by FSIS on *Listeria* testing (see Attachment 2), AMI suggests that the agency delay promulgating rules requiring *Listeria* testing until answers to the questions that have been posed are provided.

IV. Canning Regulations

AMI agrees with the comments submitted by the National Meat Canners Association. FSIS should not change the way thermally-processed, commercially sterile products are regulated. Specifically, inclusion of proposed 9 CFR Part 430.5 and the associated definitions contained in 9 CFR Part 430.1 is inadvisable and unwarranted. These sections are meant to replace the existing canning regulations contained in 9 CFR Part 318, Subpart G for meat and meat products and 9 CFR Part 381, Subpart X for poultry and poultry products.

There is no compelling rationale to make the changes described in the proposed rule when existing rules and procedures for canned foods have been effective in protecting the public health against foodborne illness. The preamble to the proposed rule states that FSIS's action is "compelled by the recent outbreaks of foodborne illness related to the consumption of adulterated RTE meat and poultry products." 66 Fed. Reg. 12590 (Feb. 27, 2001). However, none of the referenced foodborne illnesses involved thermally-processed, shelf stable foods.

Clostridium botulinum toxin is one of the most lethal foodborne toxicants. The virulence of the *Clostridium botulinum* microorganism is unparalleled. Therefore, it is entirely fitting and pleasing that detailed regulatory requirements, such as those currently codified in the Code of Federal Regulations, are prescribed to control public health threat. Although we appreciate the agency's desire to provide the industry more flexibility, the production of commercially sterile, shelf-stable food products presents unique challenges that require specific procedures and controls to prevent a potential catastrophic outcome. FSIS cannot justify replacing the existing regulations

simply on the belief that the current rules are inconsistent with FSIS's other regulatory initiatives. The existing canning regulations have been validated as effective in protecting public health. Replacing proven regulatory standards with unproven performance standards is not justifiable.

Replacing the existing canning regulations with less prescriptive performance standards could adversely affect the public health by creating unnecessary confusion and uncertainty in the industry. Section 430.5 of the proposed rule describes the performance standards an establishment must meet to achieve regulatory compliance, but the proposal is silent regarding the nature and scope of documentation a plant must have to demonstrate compliance with the performance standard. Presumably, FSIS will make the final determination regarding regulatory compliance based on the evidence that a company presents to the agency, but the company will not have the benefit of knowing the threshold of proof required by the FSIS. This regulatory approach requires proof from an establishment that it is producing unadulterated products, placing the industry in an untenable position. Less industry guidance and more agency discretion is a prescription for creating, not solving problems.

The proposed rule adds new, burdensome requirements by mandating that producers of thermally-processed, commercially sterile products address food safety hazards associated with microbial contamination in their HACCP plans. Presently, establishments producing canned meat and poultry products do not have to address microbiological hazards in their HACCP plan if the product is produced in accordance with the existing canning regulations. This exemption is permitted because sufficient microbial lethality is achieved to assure product safety. AMI does not support the notion that performance standards should replace the existing canning regulations and requests the current exemption be retained.

The proposed rule is incompatible with regulations applicable to the production of thermally-processed, commercially sterile foods other than meat and poultry products. Several manufacturers produce products in the same plant that are regulated separately by both FSIS and FDA. FDA regulations codified in 21 CFR Part 113 govern the production of thermally-processed low-acid foods packaged in hermetically sealed containers other than meat and poultry products. These regulations are very similar to the existing regulations codified in 9 CFR Part 318 and Part 381 that govern meat and poultry products. The proposed rule would significantly alter the

rules for producing meat and poultry products, thereby creating two vastly different regulatory regimes for foods that have virtually identical food safety hazards. FSIS has provided no rationale to justify this regulatory disparity.

In summary, the proposal to change the way thermally-processed, commercially sterile products are regulated is unnecessary, burdensome, and not justified based on the exemplary safety record of the industry. The proposed wholesale changes to the existing regulations are unwarranted FSIS should withdraw sections of the proposed rule that pertain to thermally-processed, commercially sterile products.

V. Draft Guidelines

The agency's "Draft Compliance Guidelines for Ready-to-Eat Meat and Poultry Products" (Guidelines) contain segments on achieving lethality standards, stabilization, and validation processes for cooked, RTE meat and poultry products. Survey respondents were asked if the Guidelines were beneficial related to each of the aforementioned topics. The survey results follow.

1. Lethality

According to the survey, 54 plants found the Guidelines useful. Importantly, 34 small establishments and all very small establishments found the Guidelines beneficial. However, 13 large and small establishments found them confusing and overly technical. Establishments that claimed the Guidelines were confusing indicated that incorporating examples would be helpful.

2. Stabilization

According to the survey, 51 of 75 respondents found the Guidelines helpful, and 15 respondents found them of little use. Respondents claiming that the Guidelines were not beneficial stated that they were confusing and overly technical. Incorporating sample protocols would be useful for some companies.

3. Listeria Testing

According to the industry survey, 55 of 75 responding companies claimed the Guidelines were useful. Ten large companies, 34 small companies, six combination companies, and all very small companies found the Guidelines useful. Ten companies found them not helpful. They cited the technical nature of the Guidelines as an impediment. In addition, respondents disagreed with the agency's random approach to testing, stating that testing should focus on areas where *Listeria* is known to be problematic. Finally, several respondents stated that the Guidelines were inconsistent with the proposal.

VI. Economic Impact

FSIS has estimated the economic impact of this proposal to be quite small. However, there are many factors that FSIS overlooked when estimating the proposal's cost. In reality, results from the industry survey indicate that the cost of this rule to meat and poultry industries would be well over $100 million, making it a major rule as classified by the Office of Management and Budget (OMB). Below, economic impact is discussed in line with the primary sections proposal: lethality, stabilization, *Listeria* testing, and thermally processed/commercially sterile products. The following points should be consideration when determining the true economic impact this proposal is likely to have on the meat and poultry industries if implemented as written.

1. Lethality

According to the proposal, the agency estimates that companies may incur additional costs in the first year in order to meet the proposed lethality performance standards. Specifically, the agency estimates that very small firms may incur costs averaging $40,210, small firms $89,380, and large firms $630,140.

According to the industry survey, 60 out of 75 companies, stated that they currently have a Critical Control Point (CCP) that would meet the proposed lethality requirement (*i.e.* 6.5 $\log_{10}$ reduction in *Salmonella* for red meat, or 7-$\log_{10}$ reduction in *Salmonella* for poultry). Significantly, 11 respondents did not have a CCP and four respondents said this portion of the

proposal was not applicable to them. Of the 60 responding companies with a CCP, 12 are large, 34 small, 10 combination (large and small plants) companies, and four were very small.

Thirty-seven respondents indicated they have validated a CCP that meets the proposed lethality requirement, as "initial validation" is defined in 9 CFR § 417.4 (a)(1).[5] Twenty-two respondents have not validated their CCP to meet the proposed lethality requirement. When asked what the average cost of validating a CCP might be, large plants anticipated $60,000, small plants anticipated $5,000, combination plants anticipated $7,440, and very small plants did not estimate cost. Some plants estimated the cost to be as much as $360,000.

2. Stabilization

According to the proposed rule, the agency believes that the cost to establishments to validate lethality and stabilization processes will be approximately $5,000, the same cost estimated to validate a HACCP plan modification.

Through the survey, when asked if respondents had a CCP in place to meet the proposed requirements, 43 answered yes, while 27 answered no, and five plants said this portion of the rule was not applicable to their operation. Of those with a CCP, 22 have validated them. The remaining 21 respondents have not validated their CCPs to meet the proposed requirements (as "initial validation" is defined in 9 CFR § 417.4 (a)(1)). Although the majority of large plants have validated their CCPs, the majority of small plants (14) have not validated their CCPs.

Respondents across all plant sizes whom have validated their CCP for stabilization estimated the cost to be $5,203. However, those who have not validated the CCP thought the cost of validating could go as high as $360,000. The average estimated validation cost was $19,939. Small processors, the ones most likely to be affected by this proposal, on average estimated it would cost $7,185 to validate a CCP for stabilization. Therefore, the proposal severely underestimates the cost of validating a stabilization CCP.

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[5] Significantly, the proposal goes beyond current requirements. Thus, even those plants with validated CCPs could face additional validation costs.

3. Listeria Testing

The proposal states,

> Depending on the individual establishment, this provision of the rule could necessitate small establishments incurring an additional $5,000 (to establish a *Listeria*-related CCP) or an additional $3,400 in environmental testing, and possibly as high as a $6,200 cost to resolve any *Listeria*-related problems. Large establishments are expected to meet this requirement by either having or incorporating a CCP addressing *Listeria* in their HACCP plan at a cost of $5,000. Very small establishments could incur an additional $5,000 cost (in CCP validation) or an additional $840 in environmental testing and possibly a $3,200 cost in resolving their *Listeria*-related problems. *Id.* at 12614

According to the survey, only 23 companies out of 75 reported having enough space to hold product while waiting for test results. Therefore, if the rule was adopted as proposed, companies would have to absorb the added cost of paying for product shipping, storage, and distressing, while awaiting test results. Companies unable to hold product due to customer demand, lack of storage facilities, or other costs are likely to ship the product prior to receiving test results, and that practice is likely to increase the number of recalls of product contaminated with *Listeria monocytogenes,* with no appreciable benefit to the public health.

Substantial costs are incurred when companies must test and hold product. The agency grossly underestimates the economic impact on the industry from this portion of the proposal. In that regard, FSIS should, but apparently has not, consider the following expenses when determining actual costs.

1) Shipping Expense: Although FSIS considered testing costs it is clear that the agency did not include the shipping costs (approximately $25 per test). This rule will affect small plants more than any other size category. Given that most small and very small plants do not have laboratories on-site, shipping costs are a substantial added expense.

2) Storage: According to the survey, 46 facilities do not have the ability to store product while awaiting test results – storage that would be

necessary given the testing frequency proposed. Only 23 respondents indicated that they have room to store product. Therefore, plants will have to find cold storage in which to house product until receiving test results. According to industry estimates, the cost of handling a single pallet averages $11.25. In addition, there is a storage fee for warehousing the product, which is about $2 daily, per pallet. The amount of business that the establishment provides to the warehouse affects this cost.. Presumptive test results for *Listeria* take approximately five days, so the cost for storing a single pallet during that period could be as much as $17.25. If the cost is multiplied by the number of pallets produced in a week, for example 400, storage cost alone would be $6,900 for one day's production. Multiplying the daily cost by five production days in a week, weekly storage totals $34,500 per week.

3) Transportation: Many storage facilities are located far from meat and poultry processing facilities. Transporting pallets to cold storage can be extremely costly. The information provided in Chart 3 below should be considered when calculating this proposal's total cost.

Chart 3. Transportation Charges for Shipment within a 500-Mile Radius

*Assuming a 1500 pound pallet taking 1 pallet position in truck. Charges are by weight (in pounds). Many factors affect delivery rates.

State	Weight	Cost Per 100 wt	Total Cost
Wisconsin – Upper	1500	0.0775	116.25
Wisconsin– Lower	1500	0.0612	91.80
Iowa	1500	0.1100	165.00
Missouri	1500	0.1100	165.00
Indiana	1500	0.0624	93.60
Michigan	1500	0.1100	165.00
Northwestern KY	1500	0.1100	165.00
Southeastern MN	1500	0.1100	165.00
Western Ohio	1500	0.1100	165.00
Illinois – Northern	1500	0.0553	82.95
Illinois – Western	1500	0.0654	98.10
Illinois – Southern	1500	0.0677	101.55

4) Distressed Product: Presumptive test results for *Listeria* take approximately three to five days. During this time product is losing valuable shelf-life. Products are rarely shipped directly to retailers. It is more common that the product is sent to a central distribution center before being moved to retail and subsequently sold to consumers. If establishments are required to test product (and likely hold the product until results are received), nearly a week of age is put on the product before it reaches distribution. Retailers want product with the maximum shelf-life possible and they will be unwilling to pay as much for a product

with 20 days remaining shelf-life as they will pay for a product with 27 days of remaining shelf-life. This cost must be taken into consideration by the agency.

5) Cost of a Test Failure: There is no documented average in the literature regarding this issue. However, for example, assume a plant averages 2.5 percent positives for its environmental tests and, assume of those approximately 1.5 percent will test positive for pathogens. Product lots testing positive for pathogens will be destroyed. Thus, subsequent line clean up and testing of five subsequent lots (while holding all products produced on those lines) is required before the line can operate normally. Therefore, the agency must also include the cost of product disposal, clean up, and additional testing in the calculation of total cost of this proposal.

The above discussion demonstrates that the FSIS estimate of $3,400 for environmental testing is greatly underestimated. Indeed, as mentioned at the outset, one large processor has estimated the costs attendant to the proposal to be about $30 million. In short, the agency's cost estimates apparently have not considered any of these other factors when calculating the economic impact of this rule on the industry – factors that can and must be considered and weighed in conjunction with the absence of any appreciable public health benefit.

4. Thermally-Processed/Commercially Sterile

According to the survey, respondents estimated validation of the lethality performance standard (12-D for *C. botulinum*) to be from $75,000 to $4.8 million. Cost estimates ranged from $14,300 to $800,000 per plant. In addition, respondents estimated the cost to comply with the "refrigerate after opening" labeling requirement, to be as much as $10,000. That cost estimate is likely low because many large establishments already have equipment in place to provide this type of labeling, or already provide this labeling on products. However, small plants that are less likely to own this type of equipment estimated compliance costs to be between $32,000 and $72,000. In short, the proposed changes would be extremely costly for industry without providing clear additional benefits to consumers.

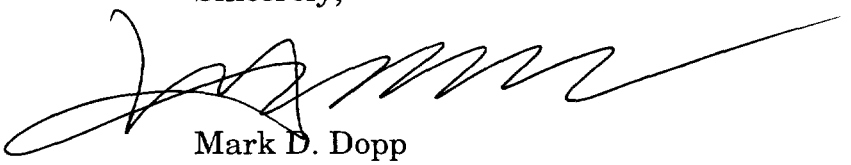
The above points should be carefully considered prior to the issuance of a final rule. Cost estimates provided by individual companies, clearly indicate that the total cost of implementing the requirements in the proposal will be in excess of $100 million. As a result, the agency should perform a cost/benefit analysis, taking human health impact into strong consideration, to determine if the changes are truly necessary. Further, the agency should clearly identify the benefits of implementing the proposed changes prior to publishing a final rule.

Concluding Remarks

AMI appreciates the opportunity to comment on the aforementioned proposed rule. Although the proposed rule is intended to minimize the risk of foodborne illness to consumers, it is at best dubious whether the rule as proposed will achieve that objective. In prescribing testing programs, including testing frequency and mandatory product testing in case of a positive environmental test, the agency has, in fact discouraged industry from testing to find the organism. Rather than return to the command and control framework it purports to have abandoned, the agency should continue to enforce the performance standard, while, consistent with HACCP principles, providing flexibility to industry in how to meet the performance standard.

Thank you once again for the opportunity to provide comments on this very important issue. If you have any questions about this letter or anything else regarding this matter, please contact me.

Sincerely,



Mark D. Dopp
Senior Vice President, Regulatory Affairs
AMI General Counsel

Attachment 1
Summary of Results
Meat and Poultry Industry
Performance Standards for the Production of Processed Meat and Poultry Products

Survey
(75 surveys covering 170 plants were returned)

I. General Information

A. Check which ready-to-eat product categories are produced by your company and provide information on the volume produced per month.
Since a significant number of respondents did not include volume information, it would be misleading to include this information. Respondents have been categorized by size as Large, Combination (reported both large and small establishments), small and very small. Results by size are given as (L/ C/ S/ VS) below. NB: these numbers do NOT represent the number of plants of that size because responses (surveys) may have represented multiple plants.

# Respondents producing product	L/ C/ S/ VS	product
29	4/ 8/ 15 /2	Sliced ham and luncheon meat
35	4/ 8/ 18/ 5	Small diameter sausage (e.g., hot dogs)
34	4/ 9/ 18/ 3	Large diameter sausage
2	1/ 1/ 0/ 0	Salads and spreads
22	5/ 5/ 11/ 1	Cooked uncured poultry
28	2/ 5/ 21/ 0	Roast beef, cooked beef, cooked corn beef
10	1/ 3/ 6/ 0	Fully cooked uncured meat patties
2	0/ 0/ 1/ 1	Jerky
9	0/ 4/ 4/ 1	Dry, semi-dry and fermented products
9	2/ 4/ 3/ 0	Thermally processed, commercially sterile
26	7/ 4/ 15/ 0	Other (bacon, unsliced hams, taco filling, pizza toppings, etc.

B. Indicate number of plants per size category covered under this survey.

#	CATEGORY
67	Large (500 or more employees)
98	Small (10 or more employees)
5	Very Small (fewer than 10 employees or less than $ 2.5 million in annual sales)

II. Lethality

(1) For fully-cooked meat and poultry items, do you currently have a **CCP that meets the proposed requirements** (6.5- log reduction in *Salmonella* for red meat or 7-log reduction for poultry) for lethality?

	Yes	No	NA
Large	12	1	1
Combination	10	1	1
Small	34	8	2
Very Small	4	1	0
Total	**60**	**11**	**4**

(2) If you answered YES to Question 1, have you validated the CCP?

	Yes	No	NA
Large	19	3	0
Combination	6	4	0
Small	20	13	1
Very Small	2	2	0
Total	**37**	**22**	**1**

(3) What was the approximate cost to validate the CCP?
From 37 respondents representing 119 plants:
Total cost: $357,500

	Respondents	Plants	Range $	Ave. $/ plant
Large	9	13	0-10,000	1,615
Combination	7	79	0-200,000	3,690
Small	20	25	0-10,000	1,760
Very Small	2	2	0-1,000	500
Total	**37**	**119**	**0-200,000**	**3,004**

(4) If you answered NO to Question 1- If the proposal is finalized, what would be your estimated cost to validate the CCP?

Note: many of the respondents identified the cost of validation to be zero, noting that they were following the FSIS regulations and so no validation was necessary. Some of these companies went on to estimate what the cost would be if in-plant validation were necessary.

From 15 respondents representing 26 plants:
Total cost: $551,600

	Respondents	Plants	Range $	Ave. $/ plant
Large	2	7	60-360,000	60,000
Combination	2	4	0-20,000	5,000
Small	11	15	0-60,000	7,440
Very Small	0	NA	NA	NA
Total	**15**	**26**	**0-360,000**	**21,215**

(5) FSIS has made available a draft compliance guidance document - do you find the information in the lethality section helpful?
*Note: The draft Compliance Document can be accessed using this link: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Doc_Rte.htm

	Yes	No	NA
Large	10	2	2
Combination	5	5	2
Small	34	6	4
Very Small	5	0	0
Total	**54**	**13**	**8**

In general, respondents found the lethality guidance helpful; respondents who had both large and small plants were equally divided in finding the guidance helpful and not helpful.

(6) If you answered NO to Question 5 what information could the agency provide that would be helpful?

Approximately one-half of those who found it was not helpful did not provide any detail as to why. Those that did respond indicated a broad spectrum of complaints ranging from not clear or understandable, to too technical. Some suggested FSIS should have provided sample protocols.

III. Stabilization

(1) Do you currently have a **CCP that meets the proposed requirements** (no more than 1-log increase of *Clostridium perfringens* and no increase in *C. botulinum*) for stabilization?

	Yes	No	NA
Large	8	3	3
Combination	9	2	1
Small	24	19	1
Very Small	2	3	0
Total	**43**	**27**	**5**

(2) If you answered Yes to Question 1- have you validated the CCP?
(Note: there should have been only 43 responses; we received 45. The two extra responses have been disregarded, as they were no in Q1 and here.)

	Yes	No
Large	7	1
Combination	4	5
Small	10	14
Very Small	1	1
Total	**22**	**21**

(3) What was the approximate cost to validate the CCP?
From the 20 respondents representing 64 plants who provided costs:
Total cost: $333,000

	Respondents	Plants	Range $	Ave. $/ plant
Large	5	8	0-10,000	2,875
Combination	4	45	0-200,000	5,556
Small	10	10	0-20,000	5,900
Very Small	1	1	1,000	1,000
Total	**20**	**64**	**0-200,000**	**5,203**

(4) If you answered No to Question 1- What is your estimated cost to validate the CCP?

Note: many of the respondents identified the cost of validation to be zero, noting that they were following the FSIS regulations and so no validation was necessary. Some of these companies went on to estimate what the cost would be if in-plant validation were necessary. Some respondents who have a CCP that meets the proposed requirements have not validated it and provided costs to do so.

From 32 respondents representing 49 plants:
Total cost: $ 977,000

	Respondents	Plants	Range $	Ave. $/ plant
Large	4	7	0-300,000	46,429
Combination	4	13	1-300,000	27,462
Small	22	27	0-108,000	7,185
Very Small	2	2	1,000-100,000	50,500
Total	**32**	**49**	**0-360,000**	**19,939**

(5) FSIS has made available a draft compliance guidance document - do you find the information in the stabilization section helpful?
*Note: The draft Compliance Document can be accessed using this link:
http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Doc_Rte.htm

	Yes	No	NA
Large	8	3	3
Combination	7	2	3
Small	31	10	3
Very Small	5	0	0
Total	**51**	**15**	**9**

(6) If you answered NO to Question 5 what information could the agency provide that would be helpful?

Approximately one-half of those who found it was not helpful did not provide any detail as to why. Those that did respond indicated a broad spectrum of complaints ranging from not clear or understandable, to too technical. Some suggested FSIS should have provided sample protocols.

Additionally we asked for data on the levels of spores of *Clostridium botulinum* and *C. perfringens* in raw meat and poultry products. No data were submitted on *C. botulinum.*

The data on *C. perfringens* can be summarized as follows:

	***C. perfringens* spores/g**			
Product	**Number of samples**	**<3**	**3-100**	**>100**
Ground turkey	154	154	0	0
Ground pork	11	9	2	0
Ground beef	6	6	0	0
Pork sausage	26	26	0	0
Total	**197**	**195**	**2**	**0**

In addition, one respondent provided data for raw batters that contain combinations of beef, pork, and poultry. They find *C. perfringens* in about 25% of the samples tested; numbers range from 10/g to about 500/g, with the majority of positive samples having 10-40/g.

IV. *Listeria* Testing

(1) Do you currently utilize one of the **options provided in FSIS Directive 10,240.2** (monthly product testing or quarterly product testing coupled with product contact and non-product contact testing)?

	Yes	**No**	**NA**
Large	9	3	2
Combination	8	3	1
Small	28	15	1
Very Small	2	3	0
Total	**47**	**24**	**4**

(2) If you answered Yes to Question 1 which option do you use?

Monthly product testing (**31**/47)

Quarterly product testing coupled with product contact and non-product contact surface testing (**14**/47)

Checked **both** (**2**/47)

	Monthly	**Quarterly**	**Both**
Large	5	2	2
Combination	6	2	0
Small	18	10	0
Very Small	2	0	0
Total	**31**	**14**	**2**

(3) If you answered NO to Question 1 do you conduct **any testing to verify control of *Listeria***?

	Yes	**No**
Large	2	1
Combination	3	0
Small	14	1
Very Small	1	2
Total	**20**	**4**

(4) If you answered Yes to Question 3 please pick the option that best represents your testing scheme
(Note: Although others replied, we have reported the answers only from the 20 who answered Yes to Question 3; one respondent indicated they tested product only **and** product coupled with surface testing.)

Product testing only

	Yes	**No**
Large	0	2
Combination	0	3
Small	3	11
Very Small	0	1
Total	**3**	**17**

Product testing coupled with product contact and non-product contact surface testing

	Yes	No
Large	1	1
Combination	1	2
Small	9	5
Very Small	1	0
Total	**12**	**8**

Environmental testing only

	Yes	No
Large	1	1
Combination	2	1
Small	3	11
Very Small	0	1
Total	**6**	**14**

(5) FSIS has made available a draft compliance guidance document - do you find the information in the *Listeria* section helpful?
*Note: The draft Compliance Document can be accessed using this link: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Doc_Rte.htm

	Yes	No	NA
Large	10	1	3
Combination	6	3	3
Small	34	6	4
Very Small	5	0	0
Total	**55**	**10**	**10**

(6) If you answered NO to Question 5 what information could the agency provide that would be helpful?

On those respondents finding the FSIS Guidance material less than helpful, the comments on what would make it more helpful ranged from no answer to make the information less technical, to the guidance does not comport with proposal (4 comments). Others disagreed with agency's random approach to testing, stating that testing should focus on where *Listeria* is.

Note: The following information is critical to determining the economic burden of implementing the proposed testing requirements as written. Please answer as many of the questions below as possible.

(7) How many ready-to-eat lines do you have...

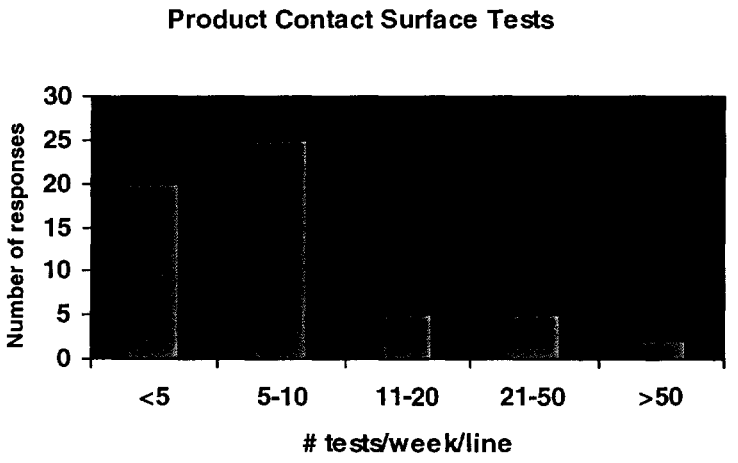
	# resp.	# plants	# lines	Lines/ plant
Large	10	17	79	4.6
Combination	11	87 (41 Lg and 46 Sm)	605	7.0
Small	42	47	192	4.1
Very Small	5	5	12	2.4
Total	68	161	888	5.5

and what is the total volume of product annually across those lines?

Insufficient data were received to determine product volumes.

(8) How many product contact surface tests per week/per line do you run?

	Range	N	Mean	Median
Large	0-75	12	17	7.5
Combination	1-30	11	7.5	5
Small	0-44	42	6.5	4
Very Small	0-5	5	1.6	0

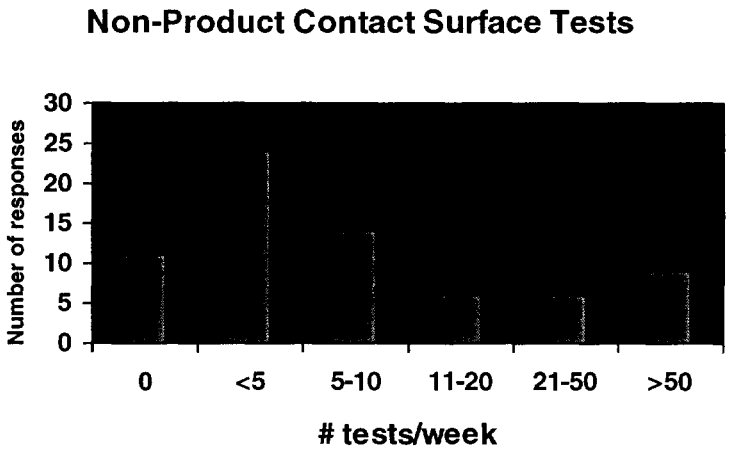


(9) Do you composite those samples?

	Yes	No	NA
Large	4	7	3
Combination	3	8	1
Small	11	24	9
Very Small	1	3	1
Total	**19**	**42**	**14**

(10) How many non-product contact surface tests per week do you run?

	Range	N	Mean	Median
Large	0-15	12	47	22.5
Combination	1.3-275	11	65.8	10
Small	0-113	42	11.4	4
Very Small	0-5	5	1.6	0



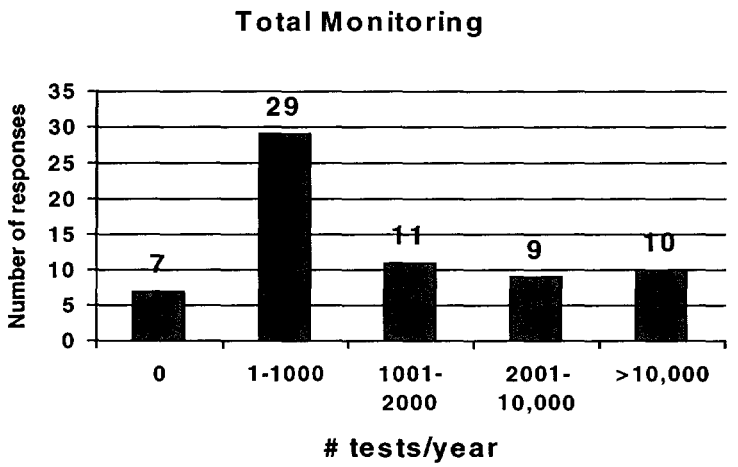
(11) Do you composite those samples?

	Yes	No	NA
Large	2	8	4
Combination	2	9	1
Small	8	27	9
Very Small	1	3	1
Total	**13**	**47**	**15**

(12) What is the total number monitoring tests per year run across all lines

Total: 424,281 range 0 – 97,700

	Range	N	# Plants	Mean	Median	Samples/ plant
Large	0-13,000	11	18	4,488	1,600	249
Combination	320-97,700	11	87	29,301	18,000	337
Small	0-12,000	41	46	1,283	500	28
Very Small	0	3	3	0	0	0



13) What do you test for on product contact surfaces?

Listeria-like	8
Listeria spp.	39
*Listeria monocyto*genes	8
All variations of the above	3
Listeria-like and *Listeria* spp.	1
Listeria spp. and *L. monocytogenes*	1

(14) What analytical method do you use?
A variety of methods were reported, including USDA, AOAC, BAM, ELISA, BAX, Tecra, GeneTrak and others. There was some misunderstanding of the question, as some reported methods such as "ATP" that are not specific for *Listeria*.

(15) What do you test for on non-product contact surfaces?

Listeria-like	10
Listeria spp.	40
*Listeria monocyto*genes	6
All variations of the above	2
Listeria-like and *Listeria* spp.	1

(16) What analytical method do you use?
A variety of methods were reported, including USDA, AOAC, BAM, ELISA, BAX, Tecra, GeneTrak and others. There was some misunderstanding of the question, as some reported methods such as "ATP" that are not specific for *Listeria.*

(17) Please provide the following information (estimates or averages are fine):

Number of pallets produced per line/per week:

Handling costs per pallet:

Storage costs per pallet/per week:

Costs of distressing/downgrading product due to extended storage:

The answers to these questions were all over the board; respondents were clearly confused about the question. Since it was not possible to assess which numbers were realistic, the data were not collated.

(18) Do you currently have enough physical space to hold the amount of product necessary to comply with the proposed testing requirements if you were to hold affected product when food contact surfaces are tested?

	Yes	**No**	**NA**
Large	2	10	2
Combination	3	8	1
Small	16	25	3
Very Small	2	3	0
Total	**23**	**46**	**6**

V. *Canning Regulations*

(1) If you produce canned products, what would be your (estimated) cost to validate the lethality performance standard (12-D for *Clostridium botulinum*).

Five of the nine respondents who produce canned products (representing 9 large and 15 small establishments) provided cost estimates that ranged from $75,000 to $4.8 million (with a range of $14,300-800,000/plant) to validate the lethality performance standards.

(2) What is the estimated cost to meet the "refrigerate after opening" labeling requirements of the proposal?

Five respondents representing 9 large and 15 small establishments provided cost estimates that ranged from $0 to $72,000. Large companies (those having either large plants or a combination of large and small plants) estimated costs of $0 to $10,000, and small plants estimated costs of $32,000 to $72,000.

(3) FSIS has made available a draft compliance guidance document - do you find the information in the canning section helpful?
*Note: The draft Compliance Document can be accessed using this link:
http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Doc_Rte.htm

Yes (2/9) No (2/9) NA (5/9)

	Yes	**No**	**NA**
Large	1	0	1
Combination	1	0	3
Small	0	2	1
Very Small	NA	NA	0
Total	**2**	**2**	**5**

(4) If you answered NO to Question 3 what information could the agency provide that would be helpful?

For those companies who found the FSIS Guidance Material unhelpful, the principal objection was that the agency did not justify why it was changing the rules.

Attachment 2
Lm Testing Questions

- Because these frequencies are not based on research but represent what the Agency believes to be minimal levels, FSIS requests comment on these proposed testing frequencies, their efficacy in preventing product adulteration, and the costs to industry. FSIS also specifically solicits information the current state of knowledge about the relationship between *Listeria spp.* on food contact surfaces and *L. monocytogenes* on the product; the appropriate timing of the test (pre-start-up or post-start up), seasonality and other risk based considerations that might be important in creating effective testing protocols; and, the testing methodologies that are currently available and the current practice and use of the tests by industry or others Agencies.

- FSIS requests comments on the proposed testing provisions and any data that would support the approach proposed. FSIS requests comments concerning whether *Listeria* positive test results on different food contact surfaces should be treated differently (e.g., positives on food contact surfaces that have undergone listericidal treatment versus other food contact surfaces). FSIS also requests comments on whether it should establish more specific requirements regarding product sampling and testing following a finding of *Listeria spp.* on a food contact surface. And, FSIS request comment on whether it should allow establishments that find *Listeria spp.* on a food contact surface to determine if the positive sample is in fact *L. monocytogenes* before having to initiate product testing.

- FSIS acknowledges that establishments that develop one or more CCPs to control *L. monocytogenes* would not necessarily be testing for *Listeria spp.* to verify the efficacy of their Sanitation SOPs and requests comments on this issue.

- However, FSIS is not aware of any research that correlates specific amounts or types of testing with specific remedial actions or reductions in contamination and welcomes the submission of any data.

- FSIS also requests comment as to whether other types of environmental testing, regular product testing, or some combination may be more effective in detecting *L. monocytogenes* contamination problems.

- FSIS requests any data that may adjust this assumption, suggest specific testing frequencies, correlate contamination risk with volume of production, or indicate what types and frequencies of testing for *L. monocytogenes* are most effective in detecting poor sanitation and possible adulteration of RTE meat and poultry products. Also, FSIS request data regarding the relationship between *Listeria spp.* and *L. monocytogenes* and how that relationship should affect any required testing provisions; For example, does a food contact surface positive for *Listeria spp.* scientifically necessitate product testing and what would negative product test results mean?

- FSIS also requests data regarding the costs and benefits of the proposed testing provisions, as well as other testing protocols.

- FSIS seeks any data correlating testing, reductions in establishment contamination, and consequent reductions in listeriosis that could be used to improve the Agency's cost/benefit analysis.