NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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USDA/FSIS
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

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97-013P
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[Docket No. 97–013P] **Performance Standards for the Production of Processed Meat and Poultry Products; 66 *Federal Register* 12590; February 27, 2001**

Dear Ms. Moore:

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products; meat, poultry, and seafood products; snacks, drinks, and juices; or provide supplies and services to food manufacturers.

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GENERAL COMMENTS

The proposed rule setting performance standards for the production of processed meat and poultry products is massive in scope and will have a very significant impact on our members who manufacture a major portion of the ready-to-eat (RTE) products in the marketplace. NFPA notes that in addition to extending lethality and stabilization performance standards to all other cooked RTE products, this proposal contains performance standards for canned products. These proposed standards have the potential to reduce the level of public health protection provided by the current regulatory requirements for thermally processed, commercially sterile meat and poultry products. The canning regulations promulgated by FDA more than 25 years ago and more recently adopted by FSIS upon our petition have represented an outstanding example of industry/agency cooperative effort to successfully

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address a recognized food safety problem. We also note that, as proposed, the *Listeria* testing requirements may also have a negative impact on public health to the extent that they act as a disincentive to aggressive testing programs needed to minimize contamination of RTE products in which *Listeria monocytogenes* can grow.

We believe that many of the provisions outlined in this proposal will not result in a positive impact on public health and are likely to impose significant economic expenditures for the meat and poultry industry. NFPA and the American Meat Institute (AMI) conducted a survey of member companies to gather industry data on the impact of this proposal. The results of this survey have been presented to FSIS and are attached to these comments. We strongly urge FSIS to carefully review all the information provided in the survey summary as it reflects current industry data based on the proposal as written.

The Agency has attempted to cover a variety of issues within a single rulemaking effort. We believe that three separate and distinct matters are melded together to the detriment of the overall docket. We strongly encourage the Agency to address as separate issues 1) lethality and cooling performance standards for cooked RTE products other than thermally processed; 2) *Listeria* testing in plants producing RTE products; and 3) thermally processed, commercially sterile products. The lethality and stabilization performance standards should be re-proposed after revisions based on submitted comments. We strongly urge the Agency to withdraw its proposal to eliminate the existing regulations for canned food products, as this is unnecessary and could have a negative impact on public health. We also urge the Agency to carefully reconsider the approach taken with respect to *Listeria* testing. The Agency should evaluate the impact that recent actions, including industry utilization of voluntary testing provisions in the revised microbiological testing directive (FSIS Directive 10,240.2), have had on *L. monocytogenes* control. If, after such evaluation and careful review of the submitted comments, the Agency determines the need to mandate such testing, we urge the Agency to significantly revise its approach, taking into account the results of the FDA/FSIS *L. monocytogenes* risk assessment, and re-publish this as a proposed rule.

The true test of the appropriateness of this proposed rule is whether or not its provisions will ultimately enhance food safety; some proposed provisions appear to present a significant burden with little or no likelihood of either enhancing food safety or providing a positive impact on any public health endpoint; and indeed, several provisions have the potential for lessening public health protections. In brief, certain provisions of the proposed rule have a greater potential "to do harm" than to enhance public health. And as we all know the first precept for advancing any public health measure – including those designed to advance food safety – is "to do no harm."

Highlights from Specific Comments

The proposed requirements for *Listeria* testing do not reflect the findings of the interagency *Listeria monocytogenes* Risk Assessment. Readily identifiable differences in public health risk

presented by various categories of products have not been considered in this proposal. For example, the requirements for frozen entrees, which do not support the growth of *L. monocytogenes*, are no different from those for pâté, which had the highest calculated relative risk on a "per serving" basis. In this regard, the Agency fails to adhere to the strategy upon which it based the Pathogen Reduction/HACCP final rule, namely to focus "...FSIS inspection on the most significant hazards and controls." Moreover, we believe that this approach will be less effective in meeting the directive by the President in May 2000 to take aggressive steps to reduce *L. monocytogenes*-related disease by 50% by 2005. We believe that a regulatory scheme that encourages firms to implement environmental testing designed to detect and eliminate *L. monocytogenes* will be more effective than the proposed mandatory minimum testing requirements.

Validation data expectations should be practical and realistic. The proposed rule does not provide adequate discussion of the Agency's expectations, nor were they revealed during the Agency's public meeting on this subject.

The Agency's stated intent to provide increased flexibility to processors is unlikely to be realized under the proposed provisions.

The compounded conservative assumptions utilized by the Agency have yielded performance standards that would be unnecessarily difficult to achieve and are unrealistic in actual practice.

The costs for hold and test programs for *Listeria* will be very significant for industry; in fact, they are likely to discourage industry testing. Our estimates (detailed below in our comments) indicate that costs of such programs for the large plants alone are likely to exceed $100 million annually.

There is no public health or food safety basis for the proposed conversion of canning regulations into performance standards; the proposed changes would not enhance food safety; in fact they could have a detrimental effect on a regulation that has proven to be exceptionally effective in minimizing food safety problems.

SPECIFIC COMMENTS

The comments below are divided into three primary sections: lethality and stabilization performance standards; testing for *Listeria* spp.; and canning performance standards. Comments are also provided on proposed changes in labeling requirements for RTE products, including canned food products.

Lethality and Stabilization Performance Standards for Cooked RTE Products

Definitions

We believe that FSIS and FDA should be consistent in their definition of "ready-to-eat food" and should use the *Food Code* definition of that term: "'Ready-to-eat food' means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form." Based on this definition, foods that would subsequently be heated would not be considered RTE, at least with regard to *Listeria* testing. We believe that FSIS should be consistent with this policy, which is followed by FDA, because it more accurately reflects consumer expectations for RTE products.

We question the advisability of codifying specific numbers in the definition of "worst-case product." FSIS proposes to codify the definition of worst-case product based on dated baseline studies conducted by the Agency from 1992-1995. This fact, combined with the Agency's use of the worst case for each assumption made in the calculation, has resulted in hypothetical worst-case product conditions that are highly unlikely, if not impossible, to ever occur. Indeed, we contend that meat with 10^6 *Salmonella* would be so obviously unwholesome that it would not be used by processors nor would it be permitted for use in USDA-inspected food production operations. Moreover, the Agency has touted the fact that *Salmonella* prevalence is decreasing as a result of industry-wide implementation of the HACCP/Pathogen Reduction rule. Assuming that *Salmonella* prevalence will decline further over time, and that reduction in prevalence also results in a reduction in the number of *Salmonella* present, the definition of "worst-case" product will unnecessarily become more and more conservative and/or the Agency will be required to amend it periodically.

Furthermore, if the specific number of *Salmonella* in worst-case product (6.7 logs/143 g in raw poultry; 6.2 logs/143 g in raw meat) is codified, there is no flexibility to derive an alternative lethality process as noted below. We believe this definition should be eliminated or redefined to remove these numbers.

Lethality Performance Standard

It is inappropriate to apply the lethality performance standard to products made from meat and poultry ingredients that have previously been processed in an FSIS-inspected establishment. We agree with the selection of *Salmonella* as a reference organism for lethality performance standards for the reasons the Agency cited. However, the proposed requirements are confusing and appear to be excessively conservative in consideration of industry practices. The most notable concern is that many processed food products use previously cooked ingredients from inspected establishments in their products without further cooking. The proposed regulations provide exemption only to thermally processed,

commercially sterile products. We respectfully suggest that the Agency intended these lethality performance standards to apply only to those establishments that are processing **raw** meat and poultry products into further-processed products, and not to the vast numbers of prepared products that are made using USDA-inspected fully cooked ingredients. Establishments that purchase and use fully cooked meat and poultry ingredients should also be exempt from the lethality performance standards, as the performance standards were met prior to release from the original USDA-inspected processing establishment. In any event, applying the proposed worst-case product assumptions to previously fully cooked meat or poultry ingredients is clearly inappropriate.

As written, the wording of the proposed rule does not appear to allow for the flexibility promoted by the Agency in preamble discussion. We agree with the need to allow alternative lethalities, but question whether the process defined by the Agency is workable. The proposed rule states that lethality processes must be validated to achieve specified low probabilities that *Salmonella* remain in finished product "assuming the incoming product is worse [sic] case." The Agency may have intended the wording of this provision to indicate solely that it used worst-case product in calculating its probabilities, but it could readily be interpreted as requiring that a processor who is attempting to establish an alternative process must assume that his starting product is worst-case product. Since worst-case product is codified as having a certain number of organisms present, how can any firm develop an alternative lethality based upon their documented ability to start with fewer organisms (as discussed in the preamble), when required to assume worst-case product?

In comments made regarding proposed performance standards for the production of certain meat and poultry products [Docket No. 95-033P], which have since been finalized, NFPA recommended that food safety objectives, rather than performance standards, should be codified. There is a food safety objective (FSO) that underlies any performance standard. For example, producing a product that presents a negligible risk from *Salmonella* and other vegetative pathogens is the food safety objective that underlies FSIS' proposed lethality performance standard. In its lethality performance standard, FSIS has quantified this food safety objective by specifying the probabilities of surviving *Salmonella* that present a negligible risk to consumers for a cooked meat or poultry product. This should theoretically allow processors flexibility to design processes to meet the FSO. In practice, it may be difficult to develop an alternative process if the Agency expects industry to adhere to the same assumptions and statistical procedures outlined in its technical paper on the lethality and stabilization performance standards. Moreover, there is no clear guidance on how much testing a company would need to conduct to establish that its raw material has initial numbers different from the Agency's baseline data.

We believe that the proposed worst-case product numbers are unrealistic based on available data and inconsistent with decreasing trends in the prevalence of *Salmonella* on raw meat and poultry. The hypothetical worst-case product numbers were based on overly-conservative statistical derivations that are not likely to represent actual situations. The Agency's technical paper on the lethality and stabilization performance standards notes that in a theoretical population of ground poultry samples, the high value of 2300 MPN/g could range, with 99% confidence, from 0.00086% to 1.279%. This would indicate that approximately 1% of 25-g portions of ground poultry could have MPN values of 2300/g. This number is then statistically transformed to 6.7 logs using a 97.5% upper confidence limit, assuming 30% recovery, and 143 g of raw product. However, according to the technical paper, 54% of the samples tested were negative, only 76 of 131 samples could be quantified, and the geometric mean of MPN-positive samples was 1.26 MPN/g (range 1.17-1.35). The probability of >4 surviving salmonellae in finished product of 0.0174% (for raw product containing 6.7 logs and given a 7-log lethality treatment) is once every 5,747 times. However, given that only 1% of ground poultry samples (or even as low as 0.0009%) hypothetically contain 2300 MPN/g, that the highest count for beef was 240 MPN/ cm^2, that most samples have much lower numbers, and that, according to FSIS, the prevalence of *Salmonella* on raw product is decreasing, we strongly believe the lethality performance standards are too conservative.

Based on the Agency's baseline data, there was a maximum MPN/g of 2300 in samples from raw ground chicken and 240 MPN/ cm^2 in beef from cows and bulls. It should be noted that these data obtained in slaughter plants are based on the maximum level of surface contamination. Obviously, the surfaces of products, which are cooked to achieve a specified internal lethality value, are subjected to much, much higher lethality.

As noted above under the "worst-case product" discussion, the starting assumption about the number of organisms present in meat or poultry ingredients artificially raises not only the performance standard itself (6.5- or 7-log reduction), but also raises the level of lethality required to meet the probability of surviving organisms which must be met by establishments who might wish to utilize the proposed option for alternative lethality. In either case, the result is that firms will be required to provide their products with a more severe heat treatment than we believe is necessary based on science. It should be noted that the worst-case numbers used to establish a requirement for a 6.5- or 7-log reduction performance standard were based on hypothetical contamination levels in 143 g of raw product. Generally a performance standard of X-log lethality assumes that a process would deliver this lethality to the cold spot of the product. Clearly the worst-case numbers of organisms are not located in a single spot, so additional conservatism is inherent in delivery of the process. Although some processors might have the technical expertise to calculate a process based on integrated lethality throughout the product, clearly this is beyond the capability of most processors. It should also be recognized that

processes are established to deliver heat treatments that account for process variability based on the individual capability for each processing line. If a 6.7-log treatment is required by regulation, processors are likely to use processes that deliver a higher lethality to assure compliance. This extra measure of heat combined with the overly conservative performance standards will likely reduce product quality due to overcooking, especially for beef products, without measurable improvement in product safety. As a result, processors may be driven to consider the manufacture of partially cooked products rather than fully cooked products in order to meet consumer expectations for product quality. We suggest that this outcome, while permissible under the regulations and perhaps necessary in order to market products that consumers desire, would be counter to the Agency's intent to improve food safety.

Given the fact that the worst-case numbers appear to be excessive, NFPA believes that sound science supports a 5D reduction in *Salmonella* and provides an adequate level of safety for cooked meat and poultry products. Further rationale for this was provided in our comments submitted on September 9, 1996 in response to Docket No. 95-033P, where we concluded the following:

> A 5-D reduction of *Salmonella* for all meat and poultry products is adequate because:
> - the numbers of pathogens on raw meat and poultry are low;
> - a 5-D process incorporates a 2-log safety factor;
> - it would also inactivate sufficient numbers of other vegetative pathogens such as *Campylobacter, Listeria monocytogenes*, and *Escherichia coli* O157:H7.

A history of successful performance is a factor that should be considered in setting the level of conservatism appropriate for establishing lethality performance standards. As a general rule, a higher threshold of conservatism is more appropriate when faced with the unknown rather than when a documented history of successful production is available. It is not uncommon for a firm processing a new product or inaugurating a new processing system to take a more conservative approach to safety in the face of the unknown. However, once a history of successful operation has been compiled, it frequently will be possible to refine the degree of conservatism necessary for a given level of assurance of product safety. If the performance standards being proposed by the Agency mean increased processing requirements for products that have long been manufactured safely with lesser processes, this seems a clear indicator that the assumptions used to calculate the performance standards are too conservative and should be reevaluated in light of this practical information. We believe this is the case with respect to requiring meat patties to increase from a 5-log to a 6.5-log process for *Salmonella.*

As previously noted, NFPA and AMI surveyed our members regarding the impact of the proposal. Data from the lethality section of the survey found that 80% of the companies responding did in fact have a CCP that would meet the proposed log reductions for *Salmonella.* Sixty-two percent (62%) of those with CCPs that met the requirements had already validated the CCP at an average cost/plant of $3,004. However, 15% of respondents indicated that they did

not have a CCP that meets the requirements, and 37% of those who did have a CCP had not validated it. Plants estimated an average of more than $20,000 to validate the CCP. When questioned about the section of the draft compliance document on lethality, 72% of respondents reported that it was helpful. Nevertheless, the discrepancy between costs to validate by those who had done so and those who estimated what the costs would be probably indicates a need for clearer guidance on Agency expectations for validation of lethality performance standards.

Stabilization Performance Standard

The requirement to demonstrate stabilization against *C. perfringens* growth in many formulated products would be costly, yet would yield no substantive public health benefit. The Agency is proposing stabilization performance standards for the entire range of RTE products when only a select group of products have historically been associated with *Clostridium perfringens* foodborne illness (e.g., roast meats and poultry and gravy) primarily in foodservice settings. Broad implementation of stabilization performance standards for *C. perfringens* and the associated validation studies to document compliance with the *C. perfringens* stabilization performance standard would be inappropriate for many processed foods. For example, *C. perfringens* is not reasonably likely to present a hazard in frozen products because spores cannot germinate and vegetative cells, which are required to produce illness, are very sensitive to freezing.

Conservative assumptions in setting the proposed stabilization performance standards are likely to create undue difficulty for industry, despite the absence of any indication of a food safety problem. Even with industry practices that have performed successfully for decades, it may be very difficult to readily validate existing procedures. If desired scientific supporting data are not readily available, they cannot be generated overnight. We would argue there is no valid scientific reason to devote significant resources to such an effort.

The proposed performance standard for zero growth of *Clostridium botulinum* is both unnecessary and unmeasurable. FSIS is proposing that processing must prevent the multiplication of *C. botulinum* and limit growth of *C. perfringens* to no more than one log. While in principle there should be no tolerance for growth and toxin production by *C. botulinum*, practically speaking we do not measure growth of the organism *per se* but toxin production. *C. botulinum* is unlikely to be present in meat and poultry, and when present its numbers are very low (ranging from <0.1 spore/kg to 7 spores/kg; summarized in Tompkin, R.B., 1980, Botulism from meat and poultry products – a historical perspective. *Food Technology* 34(5): 229-36, 257 and Hauschild, A.H.W., 1989, *Clostridium botulinum*. In *Foodborne Bacterial Pathogens*, M.P. Doyle, ed., Marcel Dekker). We believe that limiting growth of *C. perfringens* will effectively limit growth of *C. botulinum* in commercial food processing establishments. While non-proteolytic strains of *C. botulinum* may grow more rapidly than *C. perfringens* at cooler temps (e.g. 19°C), it takes days to grow at that temperature. In fact, *C. botulinum* generally

demonstrates a prolonged lag phase of several days in foods, even when inoculated at levels much higher than might reasonably be expected in meat (ICMSF, 1996, Microorganisms in Foods 5: Microbiological Characteristics of Food Pathogens, Blackie Academic). Such lengthy cooling procedures are not known to exist in inspected meat and poultry establishments. There have been no cases of botulism due to improper chilling or to an extended cooling procedure for meat and poultry products made in USDA-inspected establishments. Moreover, it is not clear to us how one would attempt to measure zero growth of this organism when enumeration methods are cumbersome and yield highly variable results.

FSIS is proposing the same stabilization performance standard for all meat and poultry products. A review of the baseline data on *C. perfringens* indicates that beef carcasses have much lower levels of contamination (no *C. perfringens* were detected in 91.7-97.4% of the samples, and 98-99% of the samples had < 100/g; 53.3% of ground beef samples were contaminated, but 99.5 % had ≤ 1000/g). Although poultry samples were more frequently positive (29% for turkey, 43% for broilers), over 99% had < 100/ml of carcass rinse. Except for ground beef, contamination prevalence and levels for ground meat and poultry were similar to those for carcasses. The estimates for *C. perfringens* in raw ground products were weighted, "taking into account the probability of selection, the volume of the establishments and the non-response." It is not possible to assess the impact of this on the calculations.

It is important to note that the baseline studies enumerated presumptive *C. perfringens*; there was no confirmation of *C. perfringens*-like colonies from plates (see FSIS MLG, Chapter 13). Thus the counts are likely to include other species of Clostridia. Because the procedure did not incorporate a step to inactivate vegetative cells, the baseline numbers cannot be used as an estimate of the level of *C. perfringens* spores, which are the concern with respect to growth during cooling (stabilization) of meat and poultry products (since vegetative cells would be destroyed by cooking, leaving only spores). Thus the "worst-case" calculation of 10^4/g used as the basis for setting the performance standard is not valid.

Moreover, these numbers of *C. perfringens*, even if they were valid for raw products, would not reflect levels of *C. perfringens* in cooked products. Spores of different strains of *C. perfringens* may vary widely in their heat resistance, and in most environments heat sensitive strains outnumber heat resistant strains. For many of the products, heat treatments may be sufficient to reduce the number of spores. Clearly the worst case of 10^4/g does not reflect the level of *C. perfringens* spores in most meat and poultry products. Industry data on products analyzed for cooling deviations previously submitted to the Agency from one meat processor demonstrated anaerobic and/or *C. perfringens* counts were low (<100/g, and usually <10/g). Data on levels of *C. perfringens* in raw product obtained by an industry survey related to these proposed performance standards (attached) in general support these numbers.

C. perfringens must grow to 10^5-10^6/g to cause illness. Given that low levels of spores are generally present in meat and poultry products and that industry practices do not result in levels of *C. perfringens* that even approach 10^4/g after cooking, we believe that a stabilization performance standard that restricts multiplication to one log is overly conservative. This proposed performance standard is likely to result in the needless expenditure of time and money to evaluate cooling deviations and to demonstrate that product is not adulterated or, alternatively, in the needless destruction of product that is safe and wholesome. Moreover, the performance standard seemingly has led to the Agency questioning the safety of product manufactured under commercial practices with a long history of safety.

We believe the Agency should reconsider the need for stabilization performance standards, including its existing stabilization performance standards for certain cooked meat and poultry products. They are not required because manufacturers of RTE products are already required by HACCP regulations to assess the potential for cooling to result in a risk to public health. Before proceeding to set any specific requirements for cooling, the Agency should obtain data on levels of clostridial spores both from the literature and from carcass sampling. Then, if the Agency proceeds to set a performance standard for stabilization, we believe that, given the low levels of *C. perfringens* spores in raw product and the number of cells required to cause illness, science supports a standard that allows at least 2- to 3-log growth of *C. perfringens*. Any stabilization performance standard that FSIS might establish should include a provision for an alternative Food Safety Objective of *C. perfringens* of 500-1000 CFU/g in cooled product.

We are unaware of a single instance in which chilling of meat and poultry products in a manufacturing facility according to current practices has resulted in foodborne illness, including illness from *C. perfringens*. To the best of our knowledge, *C. perfringens* outbreaks have been associated with food service establishments, not food processing establishments, and have been the result of inadequate hot holding or gross temperature abuse during improper cooling.

Industry costs for meeting the stabilization performance standards will be substantial. The previously mentioned industry survey found 57% of the companies responding had a CCP in place that meets the proposed requirements for no more than 1-log increase of *C. perfringens* and no increase in *C. botulinum.* Of those that have a CCP in place, only 51% indicated the CCP had been validated. The average cost per plant of the validation process was $5,203. However, estimates to validate a cooling CCP from those who have not done so averaged over $19,000 per plant. As with validation of lethality, there appears to be a need for clearer guidance on Agency expectations for validation. Furthermore, if this rule is finalized, the industry will experience significant costs, in addition to initial validation costs, for needless evaluation of cooling deviations and/or destruction of product solely as a result of the stringency of this requirement.

Maintenance of performance standards over shelf life

The intent of the requirement that processing for RTE products "...must be validated to maintain the lethality (and the stabilization) performance standards throughout product shelf-life ..." is not clear, nor are the means by which a firm would attempt to comply with the requirement. The lethality performance standards essentially require the elimination (reduction to an undetectable level) of *Salmonella*, *E. coli* O157:H7, and other pathogens and toxins that would render an RTE product adulterated. If any of these agents are found in an RTE product at any time, the product is considered adulterated. We do not disagree with this. While there is much discussion of labeling options related to shelf-life, we find no preamble discussion of the requirement to maintain the lethality (or the stabilization) performance standard throughout the shelf-life of the product.

We understand that the intent of this provision may be to provide the Agency with additional authority to take action when post-process contamination of RTE products occurs. Yet the lethality and the stabilization performance standards are met at a point in time during processing operations. For example, once a poultry product has received a heat treatment adequate to provide a 7-log reduction in *Salmonella*, the lethality performance standard has been met. Similarly, once this product is cooled to an appropriate temperature in an appropriate length of time to prevent more than a one-log increase in *C. perfringens*, the stabilization performance standard has been met. Any cross-contamination that might reintroduce *Salmonella* to the product, or any elevation of product temperature once it has left the processing facility such that *C. perfringens* can multiply to undesirable levels is unfortunate, but is a separate matter from achieving these performance standards. If the Agency's intent is to establish new performance standards for post-process contamination (which we do not believe is necessary), then FSIS should be much clearer about this and it should be a separate element of the proposed rule. Moreover, in clarifying the intent of this section, FSIS should also describe its expectations with respect to validation. In order to clarify this provision, we believe it would be most appropriate for the Agency to re-propose this section before finalizing it.

Use-by Date Labeling Issues

In determining not to proceed at this time with a requirement for "use-by" dates on labels of RTE products, FSIS correctly recognized that ".... further information regarding the potential effects of use-by date labeling is needed." For example, as FSIS noted, information is needed on current consumer understanding of use-by date labeling, on the likelihood that consumer practices will change as a result of labeling, and on the effect of changes in consumer behavior on listeriosis cases. Also, data are needed to assess the reduction in risk that would occur from this change and on how use-by date labeling would affect the production and shipment patterns of labeled ready-to-eat meat and poultry products.

We note FSIS plans, in conjunction with FDA, to present the issue of "use-by date labeling issues to the National Advisory Committee on Microbiological Criteria for Foods for its review. We concur that no action should be taken on "use by" date labeling until the NACMCF review has been completed and this additional information is available.

While we recognize that a product that does not support growth of *L. monocytogenes* does not pose the same risk as one that supports growth, currently, any RTE product containing *L. monocytogenes* is adulterated. It is not clear what FSIS' expectations are with respect to a use-by date, since even low levels of *L. monocytogenes* are not permissible under current regulatory policy. If the Agency were to establish a regulatory approach that would allow products in which *L. monocytogenes* does not exceed a specified low level during its shelf life, not only could a use-by date be established to help manage the risk from *L. monocytogenes*, but also this would encourage the development and use of new product formulations that will not support growth of the organism. For this reason, we believe such a policy that establishes a specified low level would benefit public health. Furthermore, we believe that the joint FDA/FSIS *Listeria monocytogenes* risk assessment provides the framework for such a regulatory approach.

Testing for *Listeria* Species

NFPA strongly supports development and use of processing technologies for positive control of pathogens of concern in RTE products. The most effective controls combine the ability to destroy pathogens of concern with the ability to prevent recontamination. In most cases this requires processing technologies that can be utilized on the finished product in its final packaging. Post-packaging pasteurization, irradiation and high pressure processing are promising examples of such technologies. In situations where such technologies can be applied, they offer the very best assurance of product safety and protection of public health. USDA research efforts to help develop these technologies, to help expedite their clearance, if necessary, through the food additive approval process (for irradiation, for example), and to help educate consumers to their substantial food safety benefits are all very worthwhile efforts, which NFPA and its members heartily endorse.

Unfortunately, in their current state, these technologies may not be compatible with many of the RTE foods that American consumers desire or may be cost-prohibitive at this time for smaller processors. Under these circumstances, NFPA strongly supports regulatory acknowledgement of and creation of incentives for interventions that will minimize the potential for growth of pathogens. One area that requires FSIS attention is the expedited approval of food additives. Despite the fact that FDA and FSIS agreed to regulatory changes to eliminate duplication of effort in the food additive approval process, we are aware of promising new additives that have

been approved by FDA, but are not being allowed to fulfill their promise since FSIS approval has not yet been granted.

Products subjected to an in-package lethal step to eliminate *Listeria* should be exempt from both environmental and finished product testing. (The preamble and economic impact discussions indicate that canners are effectively eliminated from the *Listeria* testing requirements; we believe that similar logic would exclude other products that are given a lethal treatment in the package. However, we believe the language in the regulation should be clearer in this regard.) Likewise, products that do not support growth of *Listeria* and are formulated to provide a lethal effect that eliminates *Listeria* also should be exempt from both environmental and finished product testing.

As we have noted on numerous occasions, industry believes the key to protecting public health with respect to listeriosis is to emphasize the need for manufacturers to develop and implement a *Listeria* control program. The essential component of a control program for RTE products not given a listericidal process in the final package is aggressive environmental testing with a disciplined root cause analysis and a corrective action program to address the results of the monitoring program. We believe that such programs are best promoted by a regulatory policy that encourages, rather than discourages, firms to test for, find, and eliminate harborages for this ubiquitous pathogen.

It is critical that the Agency address the findings of the *L. monocytogenes* risk assessment in this rulemaking initiative. We believe the Agency should reconsider its approach and re-propose this section of the rule, taking into account the key findings of the *L. monocytogenes* risk assessment. The risk assessment made clear that not all RTE food products present the same level of risk to the consuming public; consequently, it would be inappropriate and burdensome for the Agency to regulate all RTE products in the same manner.

A primary intent of the *L. monocytogenes* risk assessment was to identify those products for which additional industry and regulatory measures might yield the greatest public health benefit. Yet this proposal mandates a "one-size fits all" requirement for all RTE products for which *L. monocytogenes* is not addressed in the HACCP plan. The results of the risk assessment clearly show that those products that do not permit the growth of *L. monocytogenes* under intended conditions of handling and storage do not present the level of risk associated with products that do.

We suggest the following strategy:

Based on the findings of the *L. monocytogenes* risk assessment, we believe that ready-to-eat products that inhibit growth of *L. monocytogenes* through formulation (e.g., foods containing inhibitory compounds) or means of distribution (e.g., frozen foods) do not scientifically warrant the same criteria applied to those that do support growth. Also based on the risk assessment

findings, we believe that products that are intended to be heated or cooked present less risk than those that are intended to be and are commonly consumed without further preparation. The former need not be held to the same stringent requirements as the latter to achieve the same level of safety.

Regardless of whether products support growth or not or will be heated or not, we believe that manufacturers should implement programs (such as a prerequisite program) to minimize contamination by *L. monocytogenes*. It would also be appropriate to have an environmental monitoring program to assess the potential for recontamination of product. However, the actions taken in response to a positive *Listeria* spp. on a food contact surface could be less stringent for those types of products that present less of a risk because of factors that minimize growth or reduce the level of contamination. For example, with products in which *L. monocytogenes* cannot grow, actions in response to detection of *Listeria* spp. on a food contact surface might focus on enhanced sanitation and retesting of the surface without the need for product testing, whereas, for products in which *L. monocytogenes* can grow, repeated positives (e.g., 2-3 consecutive positives) on a food contact surface could indicate a likely harborage and would usually trigger product testing. In frozen products intended to be cooked before consumption, where growth is inhibited by freezing and low numbers of organisms that might be present would be destroyed by cooking, we see no benefit to product testing.

Likewise, we believe that the Agency should recognize that *Listeria* testing for cooked products that are intended for further processing, such as ingredients in canned products, is an inefficient and ineffective utilization of limited Agency resources for microbiological testing. In this same light, we believe cooked products that are intended and labeled for further processing as a component of fully cooked RTE foods or which are destined for use in not-ready-to-eat (NRTE) foods, should not be subject to the proposed testing requirement.

We believe that FSIS should focus its monitoring activities on products in which the organism can grow. We also believe that the Agency should devise a new strategy under which the finding of low levels of *L. monocytogenes* in products that will not permit growth to high numbers will be dealt with in a different manner than for other products. This strategy would be similar to that in other countries such as Canada. We are confident that such a strategy will have a very positive effect on public health, by giving manufacturers an incentive to reformulate or otherwise develop products that will not support the growth of *L. monocytogenes*.

The first sentence of proposed §430.4 (a) is not clearly written and is subject to more than one interpretation. Preamble discussion suggests that a firm must identify *L. monocytogenes* as a hazard reasonably likely to occur and establish a HACCP critical control point (CCP) for its control in order not to have to comply with the testing requirement. However, this provision could be interpreted as meaning that if a firm did not identify *L. monocytogenes* as a hazard reasonably likely to occur, but did establish controls (even outside of HACCP, such as in SSOPs,

or in some other prerequisite program), then environmental testing for *L. monocytogenes* per the proposed regulation would not be required.

The Agency continues to conclude that the mere presence of a pathogenic organism constitutes a food safety hazard when in fact presence without growth does not necessarily constitute a public health concern. FSIS appears to recognize this reality in its risk management of *C. botulinum* and *C. perfringens* as the proposed regulation provides for the presence of these pathogens in products, as long as growth is controlled. The results of the FDA/FSIS risk assessment suggest that controlling growth of *L. monocytogenes* can significantly reduce risk. While ice cream is not regulated by FSIS, it provides a useful case to examine on a scientific basis. Ice cream is truly a ready-to-eat product in that it is consumed directly in the form in which it is sold to the public. Recalls of ice cream have occurred because of the presence of *L. monocytogenes*, yet ice cream is not known to have ever caused an outbreak of listeriosis. This clearly illustrates that the mere presence of *L. monocytogenes* does not "cause the food to be unsafe for human consumption." We respectfully suggest that the Agency carefully consider this and the precedent regarding management of potential hazards such as *C. botulinum* as it attempts to develop regulations that are founded on science and are risk-based, in line with Agency intent to focus requirements and resources on products and processes that most require control for protection of public health.

Industry experience has shown that positive findings of *Listeria* spp. on food contact surfaces do not necessarily indicate the presence of *L. monocytogenes* on food contact surfaces or in product. Data presented by Dr. Martin Wiedmann on environmental *Listeria* testing at the FSIS technical conference in May showed that there is wide variation in the percentage of *Listeria* spp. that are confirmed as *L. monocytogenes*: 5-81% in the 5 plants in the study. In another study that Cornell University is conducting in the RTE seafood industry, the percentage of *Listeria* spp.-positives from food contact surfaces in smoked seafood plants that were confirmed to be *L. monocytogenes* ranged from 0% to 50%. In fact, in product tests 0-25% of samples that were positive for Listeria spp. were also positive for *L. monocytogenes*.

We believe the proposed approach to be fundamentally flawed as a means for minimizing the risk of listeriosis. If establishments introduce a CCP for recontamination other than a post-packaging lethality step and on this basis reduce their environmental monitoring, there is significant potential to reduce rather than enhance public health. We fear this unintended consequence of the FSIS proposal has a high potential to occur based on the following:

1. The proposed rule would not require food contact surface testing in establishments that have identified *L. monocytogenes* as a hazard reasonably likely to occur and established one or more controls in their HACCP plans after the lethality treatment. On May 26, 1999, FSIS published in the *Federal Register* a document stating that the findings from testing a range of ready-to-eat products and information from the investigation of outbreaks of listeriosis could

affect an establishment's hazard analysis; establishments were required to reassess their HACCP plans for ready-to-eat products and address *L. monocytogenes* contamination in their HACCP plans if it was reasonably likely to occur. A number of plants conducted this reassessment and added controls in their HACCP plans; presumably these establishments would be exempt from the testing required in this proposal. They may, therefore, choose to not conduct environmental monitoring.

2. Some establishments argued, in response to the May 1999 notice, that they were unable to identify one or two CCPs that could effectively prevent *L. monocytogenes* contamination of their products. However, they demonstrated that *L. monocytogenes* was a hazard not reasonably likely to occur as the result of an effective environmental control and monitoring program. Stringent, multi-faceted control programs were developed in many plants; these "prerequisite programs" involved many control points, no one of which could be considered critical to control *L. monocytogenes*. Industry feels that this is the best approach to address recontamination of products with *L. monocytogenes* when in-package pasteurization is not possible. However, given this proposed requirement to test product contact surfaces for *Listeria* spp., and to hold and test product if there is a positive on a food contact surface, a number of establishments will elect to include a CCP for *L. monocytogenes* in their HACCP plan. (FSIS estimates that the number of large plants with such a CCP will increase from 50% to100% and the number of small plants will increase from 33% to 50%.) If these CCPs are only "pseudo-CCPs," i.e., they do not fully prevent *L. monocytogenes* contamination, they will have limited effect on reducing the risk of listeriosis.

3. If establishments do not specify a CCP, it is likely that environmental monitoring programs may be modified in ways that will make them less effective. Some establishments may elect to do the minimum level of food contact surface testing because of the need to hold and possibly test product. (Establishments will likely feel compelled to hold product any time a food contact surface is tested as a result of the regulation, and therefore would reduce testing to the minimum required level in order to reduce the associated costs, which will be high.) Establishments may also feel compelled to hold other products produced on other lines the day of testing because of the potential for the test results to be applied to these products. Thus the aggressive environmental testing programs that many establishments employ to effectively reduce *L. monocytogenes* contamination could be scaled back, with a likely negative impact on public health. This is a scenario made more likely by the fact that a large number of companies do not have enough physical space to hold the amount of product that would need to be held as a result of the testing requirement.

The costs for such hold and test programs will be very significant for industry; in fact, they are likely to discourage industry testing. Moreover, we believe that a hold and test program for all food contact surface tests would be unmanageable. In our industry survey 46 out of 75

respondents (61%) representing 115 plants indicated that they did not have the space to hold product.

FSIS estimates the cost of mandatory food contact surface testing by the industry to be $5.53 million. This includes $1.28 million for HACCP plan modification, $1.75 million for testing, and $2.5 million for production adjustments. HACCP plan modification to incorporate a CCP was estimated at $5000, regardless of size of the establishment or the number of HACCP plans. The $1.28 million estimate ($5000/establishment times 257 establishments), is for the number of large establishments the Agency estimates will add a CCP. In considering the cost for sampling, the Agency established a $35 per sample rate to include shipping and handling and estimated that 50,035 tests per year will be conducted. Production adjustments involve changes to the process or facility to comply with the proposed rule, including discontinuing production of certain RTE meat and poultry products. The Agency has ranked these adjustments from minor (least costly) to the most radical (most costly) needed to remedy an establishment's *L. monocytogenes* related control problem.

We believe FSIS significantly underestimated costs to implement mandatory *Listeria* testing. First, we believe that the Agency incorrectly assumes that all 257 large establishments that currently do not have a CCP for *L. monocytogenes* will incorporate one. Second, we believe that the Agency's estimate of $5000 for incorporating a CCP grossly underestimates the cost. Although the Agency included lethality steps among its potential CCPs, clearly the Agency did not fully consider the potential company actions. We believe that some companies, primarily large establishments, will seriously consider incorporating in-package treatments such as pasteurization, high pressure processing (HPP) and irradiation to control *L. monocytogenes* in their products and would add a CCP to their HACCP plans. The costs for such processes are substantial. Although the capital equipment costs for post-packaging heat treatments are less than for HPP or irradiation, there will be significant research and development costs to develop formulations that meet consumers' expectations for quality. Costs for installation of HPP can be estimated in the range of $1 million per unit, and the limited volume each unit can handle would necessitate multiple units for establishments that produce high volumes of RTE products. Costs for an x-ray unit, which can handle much larger volumes of product, are significantly higher - $5-7 million. However, though approval of irradiation for RTE products is eagerly anticipated, the fact that FDA has not yet approved it is a possible explanation for the Agency not including this cost in its estimates.

Nevertheless, the most important costs FSIS did not address were the costs of holding product until sample results are obtained. The Agency did seek information on the need for additional storage to hold product when sampling occurs at the level outlined in the proposal. An industry survey identified 61% of respondents (and 71% of the plants producing RTE but not canned products) would incur costs for additional storage.

Costs, other than for testing, associated with holding product while awaiting test results include:

- Transportation costs
- Handling costs
- Storage costs
- Surplus inventory costs
- Distressed product costs
- Production destruction costs (In many cases product associated with positive test results will be destroyed whether it contains *Listeria* spp. or *L. monocytogenes*.)

In our survey, there was confusion about the type of information requested in relation to hold and test costs. The responses from some were clearly erroneous (e.g., numbers that resulted in a calculated 6 lbs of product per line). Others submitted information in varying formats. Wide variation in submitted costs for the above factors results in a wide range of estimated costs for hold and test programs. Some respondents provided handling costs of $9.00-11.25 per pallet and storage costs of $6.75-$9.00 per pallet. Another respondent indicated handling and storage costs of $15/day per pallet, and a third $10.70 per pallet. At least one respondent indicated that the estimated storage and handling charges did not include the charge for printing a bill of lading (an additional $2.50). One respondent provided shipping charges for shipments within a 500-mile radius of approximately $90-165 per pallet. Production estimates also varied widely. Based on some of the figures provided, we calculate hold and test costs as follows:

Cost Estimates				
Lbs / Line / Day	18,000	50,000	100,000	150,000
# pallets/line/day @1000-1500 lbs	12-18	33-50	66-100	100-150
Handling/storage (@$18/pallet)	$216-324	$594-900	$1188-1800	$1800-2700
2lines	$432-648	$1188-1800	$2376-3600	$3600-5400
4 lines	$864-1296	$2376-3600	$4752-7200	$7200-10,800
6 lines	$1296-1944	$3564-5400	$7128-10,800	$10,800-16,200
Annual costs	**$5184-23,328**	**$14,256-64,800**	**$28,512-129,600**	**43,200-194,400**

However, other respondents indicated the costs would be much higher. One respondent (that produces over 1 billion lbs of RTE product a year) indicated that the requirement for 4 tests per month would result in $17.8 million in annual costs (including transportation, handling, storage and costs to carry extra inventory). This did not include the $7 million cost incurred for distressed inventory. Another company that produces 728 million lbs of RTE product per year

estimated that to hold one day's production (over 2000 pallets of product), the cost would be $90,000-$121,000 for storage and handling. Assuming this occurs only once per month, their costs would be $1.08 million-$1.45 million annually. Yet another company has indicated that a hold and test program would cost them $30 million per year. If we were to assume that 100 of the 257 large plants that do not have a CCP for *L. monocytogenes* would implement a hold and test program, and we were to further assume that their costs are only $1 million for the program, we can see that costs for the large plants alone exceed $100 million.

As we have noted previously, we believe that *L. monocytogenes* control measures should differ based on the risk posed by the product. This includes environmental monitoring programs. Furthermore, environmental monitoring programs should be tailored to the specific establishment with respect to sites tested, frequency of testing, and actions taken in response to a positive. The finding of *Listeria* spp. may suggest the potential for *L. monocytogenes* to be present, however, as indicated by our earlier comment on finding *Listeria* spp. versus *L. monocytogenes*, clearly other *Listeria* spp. such as *L. innocua* are more common.

Moreover, since *L. monocytogenes* is so ubiquitous, sporadic contamination of the environment, including food contact surfaces, may occur but have little or no impact on product. The real problem occurs when *L. monocytogenes* finds a niche in the plant and results in ongoing contamination of product. It is only through aggressive testing of the environment that such harborage sites can be discovered and eliminated. Thus we do not feel it would be appropriate to require product testing based on a single positive *Listeria* spp. on a food contact surface. Investigation of <u>any</u> positive on a food contact surface should be done, and additional testing, that may include product testing, would be warranted for additional positives on the same surface or in the same area. However, since food contact surface positives are frequently isolated incidents, it would be a waste of resources to test product every time there is a positive on a food contact surface when those resources could be better spent on identifying real problems. It is the finding of repetitive positives (two or three consecutive findings of *Listeria* spp.) that indicates a potential harborage and warrants more in-depth analysis and product testing.

We suggest the following approach based on the scientifically sound risk assessment conducted by FDA and FSIS:

We believe that food safety is best promoted by a regulatory policy that encourages, rather than discourages, firms to 1) design products that inhibit the growth of *L. monocytogenes* and 2) test for, find and eliminate harborages for this ubiquitous pathogen.

***Listeria* testing provisions should be product type specific.** For example, for a refrigerated RTE product that supports growth, product testing may be appropriate based upon repeated positive environmental findings after corrective actions have been taken. However, provided

that an establishment has implemented a *Listeria* control program, we see no public health benefit to expending resources on product testing of the following:

- Products given a lethal treatment in the final package;
- Products in which growth of *L. monocytogenes* is controlled;
- Products in which formulation results in *L. monocytogenes* death (e.g., high salt, low moisture);
- Products that are frozen and subsequently heated.

For such products, the environmental monitoring program should specify actions such as enhanced sanitation to address the finding of *Listeria* spp. on a food contact surface.

If FSIS proceeds to mandate food contact surface testing, we urge the Agency to include in the final rule an option that provides incentive for and recognizes the efforts of firms that do more than minimal testing. The focus should be on devising a sampling scheme that is scientifically appropriate for specific types of products. We recommend a regulatory provision for an alternative to mandatory testing, as provided (at least in concept) for lethality and stabilization performance standards. If a firm has a prerequisite program and does more environment and food contact surface testing than the minimum and has a plan to address positives (e.g., root cause analysis and corrective actions), then it need not test product for *L. monocytogenes* on the basis of a single positive test result from a food contact surface.

We believe the Agency should provide an incentive for firms to reformulate their RTE products to retard the growth of *L. monocytogenes* and thereby minimize the risk their products would present in the marketplace. Products that are reformulated to prevent or retard growth, should not have to be tested. As previously stated the Agency should focus its resources and set industry requirements for those products that clearly present more risk.

We disagree with the Agency expectation that thermal processing firms will rewrite their hazard analyses to show *L. monocytogenes* as a hazard reasonably likely to occur. Thermal processes are designed for the destruction of organisms much more heat resistant than *L. monocytogenes*. Therefore, it is scientifically invalid to suggest that this organism "may cause the [canned] food to be unsafe for human consumption." The Agency suggestion that processors of thermally processed, commercially sterile products should identify *L. monocytogenes* as a hazard reasonably likely to occur in their hazard analysis would amount to a paperwork exercise, increasing cost to consumers and confusion among processors with no benefit to public health.

Performance Standards for Thermally Processed, Commercially Sterile Products

NFPA vigorously objects to the Agency proposal to replace the existing comprehensive canning regulations with abbreviated performance standards for thermally processed, commercially sterile foods and urges the Agency to withdraw this portion of its February 27 proposal. While we are generally supportive of appropriately designed and achievable performance standards, we believe the severity of the hazard addressed by the existing canning regulations along with other reasons discussed below justify their continuance in lieu of performance standards. During discussion of this issue at an FSIS public meeting on May 10, NFPA presented the industry case for leaving in the *Code of Federal Regulations* the existing regulations, which have been remarkably successful over recent decades in preventing consumer illnesses from canned foods. The unanimity of presentations by industry representatives, including a former government employee intimately familiar with the history of the canning regulations, represented a noteworthy consensus of opinion that the existing regulations are working and should not be voided, especially in the absence of any scientific justification for doing so.

Portions of our May 10 presentation are summarized below, followed by comments on several specific provisions of the proposal. A brief review of the development of federal regulations for low-acid canned foods is informative to this issue.

The canning regulations have had the strong support of the canning industry for nearly 30 years. Following a food poisoning incident in 1971 in which the failure to properly thermally process commercially canned product led to fatal consequences, the National Canners Association (now NFPA) petitioned the Food and Drug Administration (FDA) to publish new regulations to address the problem. The elements of a major new program were designed to control the primary food safety hazard associated with canning operations - the survival of spores of *Clostridium botulinum*, which could then germinate and produce the deadly botulism toxin in the anaerobic environment of the sealed can. Consumption of even small amounts of this potent toxin, in the absence of prompt administration of antitoxin, can quickly lead to paralysis and death of any consumer, not just those who might be immunocompromised or otherwise subject to special risk.

Experts from the NCA and its member companies identified the various steps in the canning process whose proper performance was essential to the manufacture of safe product. In cooperative effort with FDA, the most important features of various retorting systems, the essentials of thermal process establishment by recognized processing authorities and specific parameters of container closure were identified as mandatory requirements. Monitoring and record keeping requirements to document that factors critical to the thermal process were met, and prescribed procedures for corrective action when process deviations occurred, were also required elements of the regulation. In addition, advisory or recommended practices intended to

assure compliance with the required features were included. This strategy allowed industry flexibility to achieve a desired goal by alternative approaches most suitable for individual operations.

Along with new emergency permit requirements that provided FDA with a basis for enforcement, Good Manufacturing Practice (GMP) regulations applicable to "Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers" were published and made effective in January 1973.

Following several food poisoning incidents and one death from commercially canned meat and poultry products in the early 1970s, FSIS proposed a canning regulation in 1976, but it was never finalized. In September of 1981, NFPA petitioned FSIS to abandon its earlier proposal and to establish specific good manufacturing practice regulations that prescribe "detailed thermal processing requirements" for canned meat and poultry products.

On April 12, 1984, FSIS, noting its "... desire to provide maximum consumer protection by the most efficient means possible...", published a proposed rule in response to the NFPA petition. The option to develop comprehensive canning regulations "... was selected because it would accommodate advanced technology and would strengthen controls over canning operations to the degree deemed necessary to provide increased assurance of the safety and stability of canned product. Also, the development or [sic] regulations which are modeled after the proposed Codex Alimentarius Code of Hygienic Practice for canned foods, and which closely parallel existing FDA regulations, would serve to promote standardization and uniformity in national and international regulations." The preamble to the proposal also noted that the "... requirements and recommendations to be included in this proposal are generally recognized by the industry as essential to good canning operations and have been widely adopted."

FSIS published its final rule for canning establishments in December of 1986, and it became effective six months later. It is appropriate to emphasize that the FDA and FSIS canning regulations developed in cooperation with the canning industry have very effectively controlled the targeted serious public health concern - *C. botulinum*. Indeed, these HACCP-based regulations are widely regarded as the first and perhaps the most successful application to date of the principles of HACCP. The FSIS proposal to remove from the *Code of Federal Regulations* these industry-supported regulations and to replace them with abbreviated performance standards seems to overlook this unique background.

Our objections to the overall thrust of this portion of the FSIS proposal are numerous. In the preamble to the rule, **FSIS cites no public health basis for the proposed change.** This is not surprising since, by any measure of the effectiveness of regulatory food safety provisions, the existing regulations have been exceptionally effective in minimizing public health problems associated with canned foods. While new approaches for enhancing food safety may be

appropriate for certain foods, we do not believe the proposed changes to the canned food segment of the meat and poultry industry will yield any public health benefit. In fact, we fear that the proposed changes could have unanticipated and undesirable public health consequences that would adversely impact the very envious safety record of this segment of the food industry.

The proposed changes appear to be very likely to require **significant economic expenditures for validation of thermal processes** that are already exceedingly conservative and whose adequacy has been validated by many, many years of production of safe products. While the level of detail expected by the Agency regarding validation of lethality requirements for public health and for commercial sterility is not clear and must be clarified if the Agency should decide to proceed with its proposal, the potential costs to industry could be substantial. Yet, no public health benefit would accrue from such expenditures.

We note that in the cost analysis attached to the proposal, the Agency judged that canning facilities would incur no costs for implementation of the provisions of the rule. However, results of an industry survey indicated that the costs to validate the performance standard range from $75,000 to $4.8 million for the canning establishments that responded to the survey. While this provides only limited information, it suggests that the FSIS zero cost estimate overlooks certain major costs that would arise from these burdensome requirements that will not enhance public health.

Thermally processed commercially sterile products, which are heat processed to destroy all pathogens of concern and protected from post-process contamination by a hermetic seal, are so different from most other RTE products covered by this proposal that attempting to address all RTE products in a single rulemaking significantly complicates the total package. The overall proposed rule is rendered more difficult to follow by the need to repetitively exclude canning (there are six exceptions for thermally processed, commercially sterile products in the two columns of the *Federal Register* that address lethality and stabilization performance standards) from proposed provisions that are irrelevant to canned products.

The primary justification for the proposed change is to make the requirements for this industry segment consistent with those for other meat and poultry products. Overlooked is the fact that the change would create great disharmony with the requirements of FDA and with the recommended code of practice of the Codex Alimentarius Commission. As previously noted, uniformity of national and international requirements was one of the reasons FSIS published the rule in the first place. This is a significant issue that would introduce unnecessary complications for our members who produce FDA-regulated canned foods in addition to canned meat and poultry products and/or who export meat and poultry products to other countries. The proposed change would nullify the many years of effort aimed at achieving consistent regulations between the Agencies, despite the fact that the basic requirements for the production of safe canned foods are the same regardless of regulatory jurisdiction.

Another stated justification for the proposed change is to provide greater flexibility for industry to produce safe product in the most efficient manner. While the original FSIS canning regulations were somewhat restrictive, over the past 15 years many changes have been made, both at the request of industry and on the Agency's own volition, to eliminate unnecessary requirements, such as those for prior approval of alternative procedures that can be demonstrated scientifically to achieve the same end result. Indeed, the Agency has eliminated the many requirements in the original rule for mandatory prior approval of partial quality control (PQC) programs. After much effort, regulatory alternatives to the costly and HACCP-incompatible requirement for 10-day incubation of canned products are available. While a few additional changes along this line could be made, these can be accomplished easily with minor amendment of the existing regulations. The action proposed by the Agency is certainly not required to achieve this goal.

Upon review of the Agency's proposed version of guidelines for industry, we find that the sole change is the conversion of all required "shalls" to recommended "shoulds." We objected in the 1980's when the initial FSIS proposed rule converted many of the FDA's recommendations to requirements. We are also concerned about this current proposal to make all of the mandatory provisions advisory. As guidelines, the recommendations would not be suitable for regulatory enforcement or for compliance purposes. Processors, especially new ones or very small ones, would have no basis for knowing which of the requirements are of essential importance and which are merely examples of acceptable practices. Such a situation would seem to us to invite problems. On the other hand, if inspection personnel found fault with a processor's procedures that did not follow all of the recommended guidelines, then industry could rightfully argue that the Agency was attempting to enforce a guideline, a practice to which we have frequently objected in the past. We believe that years of experience have shown that the mix of mandatory practices and advisory recommendations in the existing canning regulations are on target and need not be changed.

We strongly object to the elimination of the regulatory recognition of the process authority. Elimination of the codified provisions for process development by processing authorities would increase the possibility that inadequate processes or procedures would be employed, especially by new and/or small processors. As processing systems become more complex and consumer demand for freshness and improved nutrient retention increase, recognized expertise in the development of thermal process schedules will become even more critical. In the face of these needs, diminished recognition of the role of processing authorities clearly could have an adverse effect of food safety. We also fear that elimination of regulatory recognition of the process authority concept could lead to an overall lessening of emphasis in this area to the eventual detriment of this industry segment. Indeed, adverse consequences for public health could arise if the elimination of these clearly understandable rules should lead any firm on its own volition to institute a questionable practice, which would readily have been recognized by a processing authority as unsafe. It is worthy to note that the development of valid thermal processes involves

much more than understanding the thermal inactivation kinetics for a particular product. For example, heat penetration rate, viscosity changes, amount of headspace, process variability and other factors can all be important in the development of safe processes. A thorough understanding of these matters is gained only through practical experience. The fine points of thermal process development and delivery are frequently not readily apparent to those without substantial experience in the field. The thermal process authority provides the requisite expertise to recommend sound processes and procedures that will protect the public health. By doing away with the regulatory significance of the process authority, it will be left to individual establishments to document that they meet the conditions of 12D for public health, as well as conditions for commercial sterility.

We disagree with FSIS setting a specific performance standard for minimum health purposes. The 12-D concept for assuring the elimination of spores of *C. botulinum* has never been codified by any Federal, state or international organization. The origin of the specific value is discussed in the preamble to the proposed rule. The state of the science of canning in the 1920's (regarding knowledge of microorganisms, capabilities of processing equipment and ability to deliver a precise process) justified very conservative assumptions that may not be warranted under some circumstances today. This high level of conservatism allows the safe use of general minimum health values that have proven their adequacy over many decades of use.

The lethality requirements for commercial sterility almost always significantly exceed 12D because of the need to destroy spores of more heat resistant spoilage organisms. Thus, the minimum health values are rarely utilized, other than in process deviation situations. Even then, it may not be necessary to know the 12D value if, as is frequently the case, the product can be reworked or reprocessed. Consequently, we view the FSIS proposal to require validation of 12D values for the host of meat and poultry products to be burdensome and unnecessary.

The original data establishing the common commercial sterility value that has been used for many years for thousands of processes for most meat/poultry products may not be easily found. The long history of safe use of these processes suggests that there is no pressing need to mount a major effort to uncover that work or to try to reproduce it. Most of the product-specific sterility values developed by individual companies, suppliers or other processing authorities are proprietary.

The extent of processes intended to be covered by this proposed section is not clear. The title of proposed § 430.5 "Thermally processed, commercially sterile products," would seem to limit its provisions to heat processed commercially sterile products; however, § 430.5(a) includes "other sporicidal lethality processing," which seems to expand coverage beyond heat processed products. If processes other than heat processing are intended to be covered, it seems odd and inappropriate that operators of such systems would have to complete a school of instruction for supervisors of canning operations. In any event, if the Agency were to proceed with

development of this rule, we would need assurance from the Agency that the use of systems and processes, other than canning, for improving the safety of meat and poultry products will in no manner be restricted or impeded.

As noted before, NFPA urges the Agency to withdraw from its proposed rule the proposed § 9 CFR 430.5 dealing with thermally processed, commercially sterile products. At a later date and under a separate docket, the Agency could undertake refinement of the existing regulations, while retaining their essential provisions. Certainly the Agency could combine and recodify the currently separate requirements for meat and poultry into a single section of the *Code of Federal Regulations*. Other modifications to eliminate any lingering restrictive requirements, along the lines of a document we shared with the Agency in 1997, could also be considered at that time. We are currently in the process of reviewing those prior recommendations to assure they are relevant to the current regulatory environment. As we have amply demonstrated over the past 20 years, we are more than willing to work with the Agency to assure the continued safety the products of this food industry segment.

Labeling requirements

We disagree with the proposed requirement for "refrigerate after opening" labeling for shelf-stable products. We are aware of only one instance in which failure to refrigerate a shelf stable product after opening has been a problem (a #10 can of cheese sauce); there have been no such problems with meat and poultry products. We understand that there are already products in the marketplace that bear this type of labeling. Despite the very limited food safety problems with these products, manufacturers who deem it useful to consumers are already providing this information.

We note that many shelf-stable, commercially sterile products are available in single serve containers; mandatory refrigeration labeling of such containers would create an industry burden, which unquestionably would provide no public health benefit. In lieu of mandatory labeling requirements that would impact only a small percentage of foods in the home, we suggest that consumer education efforts targeted at the importance of maintaining foods under refrigeration would reap the greatest benefits. This is due, in part, because such efforts could most effectively convey the need to refrigerate not only commercially manufactured products, but also, foods prepared in the home or taken home from restaurants.

Depending on the amount of lead-time provided to make the changes, the cost of compliance with these labeling requirements could be substantial. Data from the NFPA-AMI industry survey indicated the cost of the proposed "refrigerate after opening" labeling requirement to range from $0-72,000.

FSIS requested comment on the FDA guidance statements and their appropriateness for RTE meat and poultry products that are not shelf stable. We particularly would object to a mandatory requirement to apply the FDA-version of the NFPA/AFDO labeling recommendations to all canned products as it could create unwarranted concern for consumers initially, and if applied indiscriminately to all shelf stable products, could eventually be ignored by consumers. Mandated standardized wording would place an unnecessary burden on the industry when there is little evidence to suggest that consumers read every word on the label.

We appreciate the opportunity to provide input on these very important issues.

Respectfully submitted,

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NFPA COMMENTS IN RESPONSE TO SPECIFIC FSIS REQUESTS FOR INPUT

1. FSIS has proposed specific lethality performance standards for *Salmonella* in RTE Foods and for *E. coli* O157:H7 in fermented products that contain beef. FSIS requests comment on whether it should enumerate, in its regulations, lethality performance standards for other pathogens and toxins that can pose hazards to specific products or within specific processing contexts. **No, we do not see a need for FSIS to set specific lethality performance standards for other pathogens and toxins. The proposed regulations, along with the existing HACCP regulations, ensure that manufacturers must address the pathogens and toxins of concern for their products. We reemphasize that the lethality standards should apply only to products produced from RAW meat and poultry; not to precooked items used as ingredients in further-processed products.**
2. FSIS requests comment as to whether it should also apply the performance standard for *E. coli* O157:H7 to RTE fermented poultry products that do not contain beef. FSIS noted that *E. coli* O157:H7 has been found to colonize the ceca of chickens and has been isolated from retail poultry, however it has never found it in raw or ready-to-cook poultry from processing establishments. **We believe that a performance standard for *Salmonella* should be adequate for *E.* coli O157:H7 in chicken, just as it is for this pathogen in unfermented beef products. There is no epidemiologic data that suggests the need for such a performance standard.**
3. FSIS will provide compliance guides and give explicit processing instructions and time/temperature combinations proven to achieve the proposed decimal reductions of pathogens. FSIS will base its compliance guides on existing industry practices and requests comment and information regarding processing that has been shown to meet the proposed performance standards. **It may be difficult or impossible to document that some widely used processes meet the proposed decimal reductions, however, their adequacy has been proven over time. FSIS should recognize that processing requirements for reduced pH- and a_w-controlled products are likely to be less than otherwise required. We urge the Agency to accept information from industry or elsewhere on this and to include it in its guidance materials, as appropriate.**
4. To determine the proposed lethality for RTE meat products, the Agency used the highest MPN value measured for all meat products, applied a 97.5% upper confidence limit, assumed a 30% recovery, and assumed that the high value for worst-case product is 3-times the MPN because the survey data represent 3 different carcass sites combined. FSIS requests comment regarding these assumptions. **As we indicated in our comments, we believe this approach is too conservative.**

7. The Agency requests comments on whether the *C. botulinum* standard should be no (zero) multiplication as proposed. The Agency also requests any data to support a tolerance in place of the proposed *C. botulinum* standard. **As we noted in our comments, we believe that, while growth of *C. botulinum* with toxin production would constitute a serious health concern, as a practical matter, compliance with a *C. perfringens* performance standard will be more than adequate to address potential problems with *C. botulinum*. Indeed, we believe that spoilage would be an issue in meat products abused to that extent in a commercial setting, well before toxin production by *C. botulinum* could occur. Moreover, measurement of the growth of *C. botulinum* is not the general practice; production of toxin is used to indicate unacceptable levels of growth.**

8. FSIS has stated that it is possible that there can be a small amount of *C. botulinum* growth within the time of a 1-log relative growth of *C. perfringens*. Thus compliance with the proposed zero-growth standard for *C. botulinum* could impose a significant burden on industry. Consequently, FSIS requests comment on this issue, and data to support a possible relative growth tolerance in place of the zero growth proposed *C. botulinum* standard. **We wish to point out that in this case the hazard is the toxin rather than the organism. There is no effective/efficient way to monitor growth in a commercial setting. It is clear that botulinum toxin formation is a major food safety issue that would not go unnoticed. We are aware of no scientific information that would indicate how much growth occurs before toxin production. Theoretically, growth by *C. botulinum* within the time of a 1-log growth of *C. perfringens* may be possible, however, the scientific literature on time to toxin production for *C. botulinum* in foods suggests that this is not likely to occur. As we noted before, we believe that limiting growth of *C. perfringens* will effectively limit growth of *C. botulinum* in commercial food processing establishments. While non-proteolytic strains of *C. botulinum* may grow more rapidly than *C. perfringens* at some temperatures, *C. botulinum* generally demonstrates a prolonged lag phase of several days in foods. Such lengthy cooling procedures are not known to exist in inspected meat and poultry establishments.**

10. Because the frequencies for testing food contact surfaces for *Listeria* spp. 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 on 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 correct practice and use of the tests by industry or other agencies. **Much of this has been addressed in our comments. Additional thoughts may be found in our publication (Tompkin, RB, VN Scott, DT Bernard, WH Sveum and KS Gombas, 1999, Guidelines to prevent post-processing contamination from *Listeria monocytogenes*, Dairy, Food and**

Environmental Sanitation 19: 551-562). With regard to the timing of the test, in general we recommend monitoring swabs be taken after several hours production. This is more representative of conditions to which the product is exposed during production. This also would allow *L. monocytogenes*, if present in a harborage site, to work its way out of niches and contaminate the line. With respect to sampling and test methods, we are not aware that the methods currently being used (a wide variety, according to our industry survey) have been specifically validated for environmental testing. While it is possible that the reliability and effectiveness of the methods may need improvement, clearly they have been effective in finding *Listeria* in the environment. We recommend that before FSIS attempts to establish sampling plans, frequencies, performance standards, etc. their validity should be established.

11. 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 requests 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. **As noted in our general comments we urge FSIS to recognize that under a risk-based system different actions are appropriate for different types of food produced. One possible scenario for actions to be taken for different types of products in response to positive test results is noted below:**

- **Products that support growth (increase sampling to find source, possible product testing for repeats),**
- **Products that do not support growth (enhanced sanitation, no product testing),**
- **Products for which growth is controlled by freezing and which will be subsequently be heated (enhanced sanitation, increased environmental testing and process review for repeats; no product testing),**

At a very minimum, FSIS should not require product testing based on an initial finding of *Listeria* spp. on a food contact surface.

14. FSIS considered, but did not propose, requiring that the labeling of RTE meat and poultry products state the shelf-life and that shelf-life be based on product safety. Further information on consumer understanding of use-by date labeling, likelihood that consumer practices will change, and on the effect of changes in consumer behavior on listeriosis cases is needed. FSIS does not have information on how use-by date labeling will affect production and shipment patterns of labeled RTE meat and poultry products and the structure

of the industry. FSIS requests comments on all of these issues and on the feasibility of requiring "use-by" date labeling on RTE meat and poultry products. **NFPA supports use by labeling on products that require it for safety. If a product does not support the growth of *L. monocytogenes*, the length of time that the product is held under refrigeration is not relevant. And development of science-based "use by" labeling for these products is not necessary.**

If growth is possible, the growth rate depends on storage temperature. Manufactures of RTE products practice tight temperature controls during storage to prevent spoilage and extend shelflife. In many instances, this temperature is at or near the lower limit of growth for the organism. However, temperature control after product leaves the manufacturing facility varies considerably, with a certain number of retailers and consumers holding product at abusive temperatures. If potential abuse temperatures were used, shelf life would be extremely limited (days), which does not provide realistic useable shelf life for consumers and retailers. Moreover, it is not possible to set a use by date based on growth of an organism that cannot be present.

15. FSIS is proposing that the labeling of RTE products state that the product requires refrigeration after opening as applicable. FSIS has considered the FDA guidance statement "Important—must be kept refrigerated to maintain safety" or "Important—must be refrigerated after opening to maintain safety." FSIS requests comment on the statements and their appropriateness for RTE meat and poultry products, which are not shelf stable. **This issue was covered in our specific comments.**

16. FSIS is proposing a general and not a quantitative standard for commercial sterility in this document but requests comment on whether a quantitative standard is necessary. **NFPA strongly urges FSIS to drop any further consideration of a quantitative standard for commercial sterility. Indeed, we urge FSIS to leave the canning regulations intact.**

17. FSIS specifically invites comment as to whether and in what form the existing requirements for thermally processed, commercially sterile meat and poultry products should be retained. **NFPA strongly urges FSIS to withdraw its proposal to convert canning regulations into performance standards. These regulations have been remarkably successful in controlling the public health concern for which they were originally designed; there is no public health basis for dismantling them.**

18. 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. **We believe that the voluntary approach embodied in FSIS Directive 10,240.2 and other voluntary programs established by industry should be allowed to prove their worth. Regulatory compliance-based programs that serve as disincentives to aggressive company actions to find and eliminate *L. monocytogenes* in plants producing products of concern are contrary to the interest of public health.**

Rather, programs that provide incentives for elimination of pathogens in the plant environment or for altering products to reduce their risk potential will be much more effective in serving the public interest. We welcome the opportunity to work with the Agency in establishing appropriate programs.

19. FSIS is aware of no research linking volume of production with the likelihood of product adulteration by *L. monocytogenes* and has assumed that insanitary establishments producing higher volumes of RTE meat and poultry products would be more likely to adulterate more product and thus pose more risk to public health. As a result, FSIS has proposed a progressive series of testing frequencies to protect consumers from adulterated product and to minimize the cost of testing for small business. 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 insanitation and possible adulteration of RTE meat and poultry products. Also, FSIS requests 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?). **Volume is not an indicator of risk. We recognize that if there is a contamination problem in a high volume operation it is likely to affect more product than in a lower volume operation; however, the controls implemented by a facility are much more important than size as an indicator of potential risk to public health.**

Finding *Listeria* spp. is merely an indicator. We have previously addressed the issue of *Listeria* spp. versus *L. monocytogenes*. A presence/absence test provides little information on a single isolation. One must look at trends of isolation. Furthermore, there is compelling evidence that not all *L. monocytogenes* strains are virulent; only a few serotypes cause most cases of listeriosis. This is an area currently being studied by a number of researchers. However, the fact that many strains isolated from the plant environment appear to be isolated infrequently from clinical cases is further reason to not require product testing based on a single *Listeria* spp. positive on a food contact surface.

22. It is possible that better data are available for deriving hypothetical worst-case products and corresponding performance standards. FSIS specifically requests any data that would support requiring different lethality performance standards to achieve certain public health benefits. **It is inappropriate to apply the same performance standard to a formulated product that utilizes fully cooked or canned meat as an ingredient that would be applied to the same product manufactured from raw meat. Different lethality performance standards are definitely needed for product that was previously cooked. The proposed rule does not make the distinction and it definitely should.**

24. FSIS requests comment and scientific data relative to whether the Agency should revise the existing and proposed stabilization performance standard for controlling *Clostridium botulinum* and *Clostridium perfringens*. **This has been addressed in our comments.**

25. FSIS will publish compliance guides for small business that will include detailed instruction on how to comply with the proposed performance standards for all categories of RTE meat and poultry products. FSIS requests comment on other measures it could take to mitigate the economic impact of any final regulations. **Our comments on the guidance document follow.**

NFPA COMMENTS ON DRAFT COMPLIANCE GUIDELINES FOR READY-TO-EAT MEAT AND POULTRY PRODUCTS

FSIS has issued Draft Compliance Guidelines for RTE meat and poultry products to assist establishments in understanding the requirements of the proposed performance standards rule published on February 27, 2001. NFPA supports the need for guidance materials. However, experience has shown that compliance "guides" will be viewed as requirements by some portion of inspection program employees. This gives industry reason for concern. We urge the Agency to work with industry to ensure that the guidance will not result in problems for companies that use alternative, scientifically supportable processes and procedures. Furthermore, we urge that the Agency retain on the guidelines cautionary language indicating they should not be used for regulatory enforcement or compliance purposes.

We believe that as meat and poultry regulations are converted into performance standards, compliance guidelines play a very important role by serving industry as "safe harbors." Many processors do not have the technical support needed to independently conduct the scientific validation work required to develop or optimize a process and still assure product safety. NFPA provides these services to its members as new products are introduced, issues arise, or new hazards are identified. However "safe harbors" are used in most applications and are necessary for many small processors, who do not have the internal expertise or financial wherewithal to avail themselves to the flexibility the Agency is intending to provide in the performance standards.

GUIDELINES FOR COOKED MEAT PRODUCTS

The time temperature guidelines for cooked beef, roast beef, etc. that have been published on the FSIS website and that are reproduced in this draft guidance have been used successfully by industry for many years to produce safe, quality products. Similarly, the temperatures specified for cooking poultry products have also been used successfully for safe, quality poultry products. FSIS indicates that times derived from an article to be published on modeling non-linear survival curves to calculate thermal inactivation are significantly higher than those published in the current guidance and requested comment on the new time/temperature combinations for RTE poultry. We have not yet seen the publication and cannot comment specifically on the derivation of the times and temperatures. However, we believe that the existing times and temperatures have proven adequate. Considering the levels of *Salmonella* in poultry, we believe that there is sufficient margin of safety in the current processes and see no reason to increase the processes.

The performance standards and the guidance document are intended to apply only to meat and poultry-containing components of products. However, in some establishments the inspector has indicted to plant personnel that sauces, vegetables, rice and other non-meat components must

achieve the same lethality. We believe that clarification should be provided in this guidance document and perhaps in a notice to inspectors that lethality treatments for other components should be determined by the establishment; they are not required to meet these guidelines.

HEATING DEVIATIONS AND SLOW COME-UP TIME

FSIS has expressed concern in this guidance document about potential multiplication of pathogens in product for which there is a heating deviation. While theoretically a product that is subject to a slow come-up time may experience extended time in the temperature range for pathogen growth, we question the statement that multiplication may be such that re-cooking may be ineffective. A number of factors must be considered, including the initial microbial load (FSIS data indicate these numbers are likely to be low), whether the pathogens on the product are likely to be on the surface or internal, the time at which the product remains in the growth range and other factors. We concur with the Agency that establishments may want to use computer modeling to estimate the relative multiplication of bacteria and that establishments should ultimately rely on the expertise of a processing authority to determine the appropriate disposition of the product. However, we disagree with the Agency on the role of sampling in such instances. While it is true that we cannot sample for all possible bacteria, an experienced microbiologist can determine which organisms are of concern and thus should be tested for, as well as determining an appropriate sampling plan. While microbiological testing should not be the only information used to evaluate the safety of a product that has undergone a heating deviation, we believe it can provide some very useful information that can assist in determining appropriate disposition of the product.

CUSTOMIZED PROCESSES

FSIS indicates in the compliance guidance that establishments or their process authorities may develop customized processes use alternative lethalities that meet the performance standards. The Agency then states that "statistical calculations on results obtained from sampling alone are not sufficient to demonstrate that product satisfies reduced initial product conditions." The Agency then goes on to state that the "demonstration should be based on scientific rationale, supported by experimental data." Yet the Agency's own lethality performance standards are based on statistical calculations obtained from sampling carcasses. We believe that the Agency should clarify its thinking on this point.

STABILIZATION GUIDELINES

We have noted in our comments that we believe the stabilization performance standard is overly conservative given the levels of *C. perfringens* spores found in raw meat and poultry and inappropriate for many products. Nevertheless, we believe that it is important to properly cool products, as gross mishandling could result in spoiled and possibly unsafe products. We are

unaware of a single instance in which chilling of meat and poultry products in a manufacturing facility according to current practices has resulted in foodborne illness, including illness from *C. perfringens*. Industry operated for a number of years under FSIS Directive 7110.3, which provided times and temperatures for controlling cooling. Some of the provisions in that Directive have been incorporated into these guidelines. However, other provisions were considered to be scientifically unsupportable and have been excluded. We believe that the low level of clostridial spores in meat and poultry is the primary reason why such established practices have been successful. The Agency should obtain data on levels of clostridial spores both from the literature and from carcass sampling before determining the need to proceed with specific cooling performance standards. In the meantime, the cooling procedures outlined in FSIS Directive 7110.3 should be considered acceptable.

Furthermore, we believe that any cooling guidelines established by FSIS should take into account the fact that *C. perfringens* does not grow below 55°C and proteolytic *C. botulinum* does not grow below 50°C. Although non-proteolytic *C. botulinum* can grow as low as 3.3°C, it is found in meat in the US with a lower frequency than the proteolytic strains, which themselves are found very infrequently and at very low levels. Growth at the lower temperatures would be very slow, allowing for longer cooling times in the lower temperature range. FSIS recognizes this in its cooling guidance but is overly conservative in the amount of time allowed for a slow cool. We believe that scientific justification could be developed for the slow cooling processes that certain segments of industry have used for years with no problems.

As we noted under the lethality section, in some establishments the inspector has indicted to plant personnel that sauces, vegetables, rice and other non-meat components much meet the cooling performance standards. We believe that clarification should be provided in this guidance document and perhaps in a notice to inspectors that cooling processes for other components should be determined by the establishment and are not required to meet these guidelines.

COOLING DEVIATIONS – Computer modeling and sampling

FSIS indicates in the guidelines that product sampling may not be the best recourse for determining product disposition when there is a cooling deviation. The Agency appears to put greater emphasis on computer modeling as a tool to assess the safety of product after a cooling deviation. We respectfully submit that both sampling and modeling can be useful in determining the appropriate disposition of product. The ARS has recently released two new cooling models, one for *C. botulinum* and one for *C. perfringens*. However, both models clearly state that the models should be validated in each specific food of interest. Thus, until such validation studies are conducted it would appear that the models could have very limited acceptance by the Agency. We believe that the models can be used to give an indication of whether there is likely to be significant growth of *C. perfringens* or *C. botulinum*. In addition, sampling for *C. perfringens* using an appropriate sampling plan such as outlined by ICMSF can provide

additional assurance that the conditions the product has been exposed to have not compromised safety. The sampling data would be a reflection of whether or not spores of *C. perfringens* were present after cooking and able to germinate and grow during cooling.

FSIS indicates that if computer modeling suggests that the cooling deviation would likely result in more than one log increase of *C. perfringens*, the establishment can choose to recook or to sample the product. The Agency provides guidance on recooking but no guidance on sampling. We believe that sampling would be appropriate to determine the disposition of the product and believe the Agency should provide further guidance in this respect.

COMPLIANCE GUIDELINES FOR LISTERIA TESTING OF FOOD CONTACT SURFACES

We note that the compliance guidelines described here and the requirements of the proposed rule are inconsistent. We find this guidance much more realistic and useful. In our comments we have indicated that product testing should not be triggered by a single positive on a food contact surface. The guidance suggests that "once the product contact surface is positive for the number of samples indicated in the HACCP plan for *Listeria* spp., the next lot of product produced on the line should be sampled." (Emphasis added) Although we believe this program would not necessarily be part of the HACCP plan, we agree that actions to be taken on finding positive should be spelled out in an establishment's environmental monitoring program and that such actions may not require product testing based on the initial positive on a food contact surface. Furthermore, in the May 1999 FSIS Guidance on *Listeria* there is an attachment with examples of environmental monitoring programs. FSIS has indicated that these are acceptable programs that may be employed by establishments. None of these examples indicate that product testing must be initiated after a single food contact positive.

As we have indicated in our comments, we believe that the type of environmental sampling program should be dependent on the level of risk presented by the product. We have worked with a number of companies who have implemented *L. monocytogenes* control plans that include environmental monitoring. A wide variety of approaches have been taken in these monitoring programs, and all these programs appear to be appropriate and effective. Thus we believe that industry, the regulators and consumers will be best served by guidance that provides flexibility. We would appreciate the opportunity to continue to work with the Agency on such guidance materials.

GUIDELINES FOR THERMALLY-PROCESSED, COMMERCIALLY STERILE MEAT AND POULTRY PRODUCTS

We have urged FSIS to leave the current regulations in place. This would obviate the need for this guidance, which we find to be an inadequate substitute for the existing comprehensive canning regulations.

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...

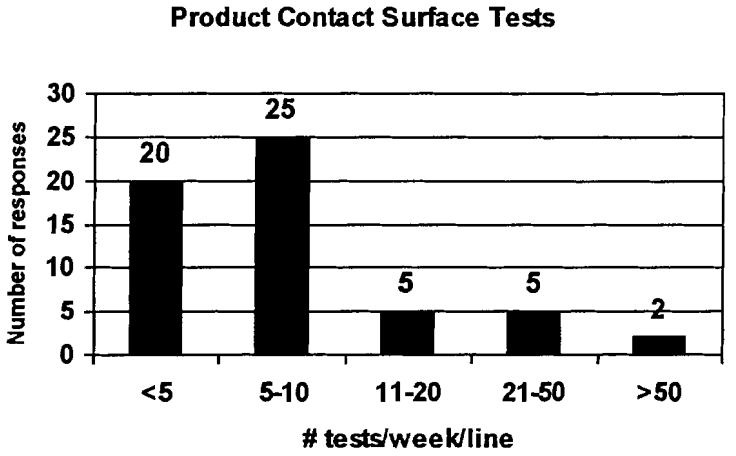
	# resp.	# plants	# lines	Lines/ plant
Large	10	17	79	4.6
Combination	11	87 (41 Lg and 46 Sm)	605	7.0
Small	42	47	192	4.1
Very Small	5	5	12	2.4
Total	68	161	888	5.5

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

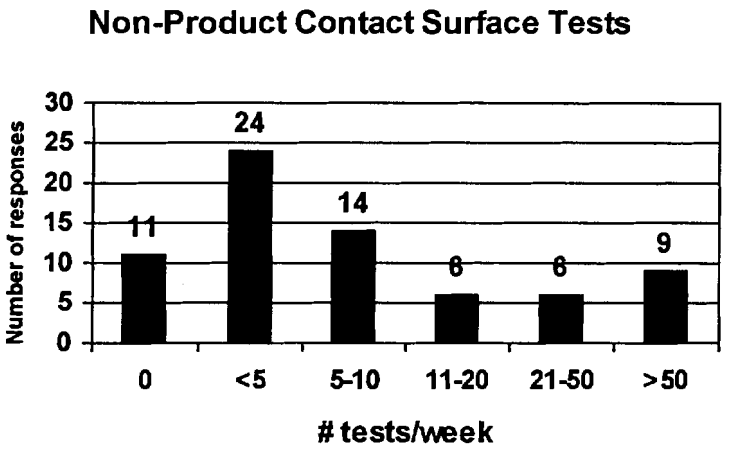


(9) Do you composite those samples?

	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



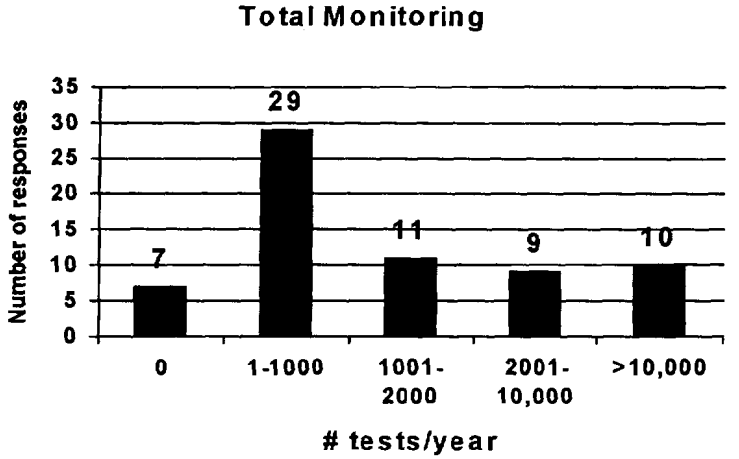
(11) Do you composite those samples?

	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.