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Refrigerated Prepared Foods

September 7, 2001

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97-013P-2708
97-013P
R.B. Tompkin

FSIS Docket #97-013P
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex
300 12 St., SW
Washington, DC 20250-3700

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

To whom it may concern:

This letter is in response the proposed rule: 9 CFR Parts 301, 303, et al, published in the Federal Register on February 27, 2001. The comments are being submitted on behalf of ConAgra Foods and ConAgra Refrigerated Prepared Foods.

ConAgra Refrigerated Prepared Foods is a leading producer and marketer of fresh and processed meats and meat alternatives under an array of brands including Armour, Butterball, Cook's, Decker, Eckrich, Healthy Choice, Hebrew National, Lightlife and Swift Premium. ConAgra Refrigerated Prepared Foods is part of ConAgra Foods, Inc., North America's largest foodservice manufacturer and second largest retail food supplier, with annual sales in excess of $27 billion.

Our response consists of several attachments including:

<u>*Listeria monocytogenes*</u>

- Response of ConAgra Foods to the Proposed Rule for *Listeria* Testing.
- Control of *Listeria monocytogenes* in the Food Processing Environment by R. B. Tompkin

<u>Chilling requirements (stabilization)</u>

- Notes used by R. B. Tompkin to comment on the chilling requirements for cooked meat and poultry products: public meeting, Washington, DC, May 9, 2001
- Response of ConAgra Foods to the rule on chilling and reheating cooked meat and poultry products

Cooking requirements (lethality)

- Response of ConAgra Foods to the rule on cooking meat and poultry products

Fermented products

- Response of ConAgra Foods to the proposed lethality performance standard for fermented products

Miscellaneous

- Response of ConAgra Foods to certain questions and concepts posed in the proposed rule

We respectfully request that consideration be given to these comments.

Yours truly,

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Notes used by R. B. Tompkin to comment on the chilling requirements for cooked meat and poultry products

Public meeting, Washington, DC – May 9, 2001

First, the international implications of the cooling requirements should be considered. Can we as a country defend the requirements based on available epidemiology and science? I believe you will agree that the answer is no when the following information is considered.

1. *C. perfringens* is most commonly associated with cooked meat and poultry, stews, etc.

2. The Center for Science in the Public Interest (CSPI) listing since 1990 shows:

Dairy Products	1
Soup	1
Tuna Salad	1
Mexican Foods	11
Beef	13
Corned Beef	2
Chicken and Turkey	7
Pork	3
	39 reported outbreaks

3. Yes, *C. perfringens* is a public healthy concern, but: has an outbreak ever been traced back to a cooling defect in any state or federally inspected plant?

   None of the 39 outbreaks reported since 1990.
   I don't know of any for certain.
   Blankenship paper?

4. So, why has FSIS become increasingly concerned about the rate of chilling cooked products?

5. Challenge tests and the resulting predictive models:
   - Challenge tests show *C. perfringens* multiplies rapidly in the few products tested when held in the range of 90 - 120°F.
   - $NaNO_2$ has little or no effect in high moisture, high pH products
   - Our tests confirm the results from the USDA-ARS.

6. FSIS estimates derived from the baseline data lead to a worst case of 10^4/g *C. perfringens* in the raw meat blend.

   If, after cooking, there is a 1 $\log_{10}$ increase then some of the product would exceed 10^5/g, "but the amount of product that would exceed 10^6/g would not be significant".

7. The FSIS conclusion that meat and poultry products cooked under federal inspection could be as high as 10^5/g and maybe 10^6/g under normal conditions is a scary thought and has been reflected in FSIS policies over the past 6 years or so (i.e., no > 1 log increase during chilling).

8. Again, knowing the normal variation that occurs in chilling cooked meat and poultry, we should have seen numerous outbreaks over the past 40-50 years. Certainly, power outages are not new.

9. History shows this is not true.

   Why? Why haven't we experienced outbreaks over the past 35 years from these products?

   That is the question should have been explored and answered by FSIS <u>before</u> issuing its cooling requirement.

   I can't imagine how much money has been spent to modify plants to meet the tighter requirements.

   Furthermore, I am certain large quantities of safe, wholesome food have been destroyed because the chill rate was beyond the 1 log increase predicted by the ARS model.

   I also suspect the impact has been the greatest among smaller establishments who lacked the technical support to challenge the FSIS determinations.

10. Our laboratory has been investigating why products from inspected establishments have not been or only rarely implicated in illness due to slow chilling.

11. What have we learned?

   - First, let's look at the baseline data.

     1. The baseline studies did not look for the number of *C. perfringens* spores. (Explain what this means).
     2. The agency assumed the "*C. perfringens* counts" reported in the baseline studies for raw meat and poultry also would apply after cooking.
     3. The analysis did not include confirmation for *C. perfringens*.
        All black colonies surrounded by a 2.4 mm opaque zone were assumed to be *C. perfringens* and counted.

     To summarize, the data from the baseline studies can not be used to estimate the number of surviving *C. perfringens* spores in freshly cooked meat and poultry products.

12. What is the spore level in raw meat and poultry?

   <u>Reported data from the FSIS baseline studies for raw ground turkey</u>:

	No. samples	% +	SE
Raw ground turkey	296	2.81%	3.3

   The 78 positive samples had a $\log_{10}$ mean = 2.08

These are among the data used by FSIS to establish the estimated level of spores in cooked meat.

To check the validity of the FSIS data for raw ground turkey we examined raw turkey from 3 plants. A total of 154 samples were analyzed. All of the samples yielded <3 spores/g and demonstrate that the data from the baseline studies were not valid.

13. In a study we performed for the US military to determine the level of spores in raw meat and thus the irradiation dose that would be required to produce safe, stable military rations we conducted a survey covering plants throughout the US and Canada. The samples were intentionally selected to represent the worst case (i.e., bloody neck area of pork and beef carcasses). The data were published in Appl. Microbiol. (1966).

    1964-65 survey for US and Canada beef, pork, chicken
    2,358 samples (bloody neck area of beef / pork and chicken)
    77% ≤ 3 PA spores/g
    mean = 2.8 PA spores/g

    C. perfringens would have been detected and counted, if present.

    A repeat of that survey today would likely yield fewer spores due to improvements in slaughtering practices in the past 35 years or so.

14. Over the past several years we have examined 53 lots of cooked meat and poultry products following cooling deviations.

	C. perfringens/g		
No. Samples	≤10	11-100	≥100
340	336	2	2 (110 and 140)

    Initially, we analyzed for anaerobic plate count but FSIS had trouble interpreting these results.

	Anaerobic plate count/g		
No. Samples	≤100	100-10,000	10,000 – 20,000
582	425	55	2

15. We also have determined through challenge studies that *C. perfringens* dies during refrigeration storage. This could help explain why products cooked in federal establishments have not been implicated in illness due to growth during cooling. If growth had occurred the pathogen numbers would have decreased during subsequent refrigerated storage to levels too low to cause illness.

    1 D in 24 hours > 2 D in 7 days Same results at (33, 40, 50°F)

16. Conclusions:

The FSIS cooling requirements are not based on a solid, scientific footing.

The panic that appears in the FSIS material for cooling is not warranted. Limiting to no greater than a 1 log increase is not necessary to ensure public health.

C .perfringens is not a hazard that is reasonably likely to occur.

The majority of *C. perfringens* outbreaks occur due to poor temperature control at foodservice and in the home.

<u>Recommendations</u>:

Change the performance standard from "no more than 1-$\log_{10}$ multiplication of *C. perfringens*" to "no greater than a 3 log increase <u>or</u> no greater than 500/g at the time the product is released for shipment".

FSIS is of the opinion that the risk of *C. perfringens* illness is best controlled through processes based on:

- Challenge tests
- Predictive modeling

I suggest that more is needed and that is a reality check based on historical, commercial experience and a critical review of epidemiological data.

Furthermore, in the event of a deviation, sampling a suspect lot is a valid option. The sampling plan and criteria could be:

> $n = 10$, $c = 3$, $m = 100/g$, $M = 500/g$ for *C.perfringens* using the current method in the Compendium of Methods, BAM, or MLG.

Finally, the restrictions being imposed by FSIS for when cooked products are browned, smoked, caramelized, seared/charred, post pasteurized, etc. have not been associated with increased risk and should be permitted as before the original guidelines were first issued.

The no-growth requirement for *C. botulinum* is an unrealistic expectation. There are too few laboratories in the US to do this work and, therefore, the requirement can not be verified.

Don't worry about botulism and concentrate on *C. perfringens* as the target organism.

There have been no incidents of botulism in the United States due to poor chilling of perishable meat or poultry products produced under federal or state inspection.

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September 2, 2001

Response of ConAgra Foods to the Proposed Rule for *Listeria* Testing

A. The purpose of the Listeria testing proposal is to reduce listeriosis among consumers of ready-to-eat (RTE) foods.

This is a goal that industry shares. How this goal can be best met requires a full understanding of the issues. This response to the proposed rule provides comment on the proposal and provides alternative options that could be applied.

B. Two recent estimates have been provided by the federal government on the relative importance of RTE meat and poultry products as vehicles of listeriosis.

1) Federal Register notice for the proposed rule, Table 9, page 12627.

Food source	Cases	Deaths
All foods	2324	480
Meat and poultry products	186	38
RTE meat and poultry products	167	35

2) Federal Register notice for the proposed rule, pages 12624-8.
Estimate from the FDA-USDA draft risk assessment, page 12628, column 1.

Food source	Cases	Deaths
RTE meat and poultry products	1660	322

It appears that the proposal is intended to reduce the number of cases from a range of 167 – 1660 to some smaller number. Likewise, the number of deaths would be reduced from a range of 35 – 322.

The discrepancy in the values (e.g., 167 to 1660) indicates the difficulty in estimating the relative role of specific foods as vehicles in listeriosis. The discrepancy is remarkable considering the total number of cases in the US from all sources has been estimated to be about 2500 cases (Mead et al, 1999).

The range in values indicates that the improvement in consumer protection from the proposed regulation is very uncertain, with no specific goal being stated in the proposed rule.

A proposed rule of this magnitude should provide an estimate of the expected improvement in consumer protection.

Furthermore, the proposed rule should reflect information derived from the FDA/USDA and FAO/WHO risk assessments for *L. monocytogenes* in RTE foods (FAO/WHO, 2001; FDA-USDA, 2001). The FDA/FSIS risk assessment should have been used to generate information that would provide guidance on risk management options and to estimate the reduction in risk before issuance of the proposed rule.

The proposal makes the assumption that the emphasis of the rule should be directed toward larger establishments due to the large number of consumers exposed if contaminated products are produced. This assumption fails to recognize that the vast majority of listeriosis consists of isolated cases and are not associated with outbreaks. This comment is not intended to re-direct attention away from the responsibility of larger plants. Rather, it is intended to point out that the true source of the isolated cases is not known. If the proposal is to reduce the incidence of listeriosis to a lower level (e.g., 2.5 cases per 100,000 population per year), then the source of the foods deemed responsible should not be assumed.

Information about the responsible foods may come from a variety of sources (e.g., epidemiologic studies, risk assessments). Even these require critical examination to verify their validity. Consider, for example, the recent FDA/USDA risk assessment for *L. monocytogenes* in RTE foods. It was estimated that frankfurters are a significant source of listeriosis in the US. Yet, to date, there evidently have been very few matches between the clinical isolates identified through the FoodNet system and the isolates detected in contaminated franks by the FSIS monitoring program, the notable exception being the outbreak in 1998-1999.

C. Reducing listeriosis is an important societal goal but it is unlikely this proposal will help achieve this goal for the following reasons.

1) Less environmental testing will be conducted.

- Although not mandatory, industry will have to hold all RTE product produced by the establishments on the day that samples are collected because a positive result requires testing implicated product.

- Most plants have limited capacity to store finished product and will have to ship product to an outside warehouse to retain control until a report is received from the testing laboratory.

- The large number of lots on hold will increase the likelihood of errors in maintaining control over all the affected lots until officially released.

- There will be substantial financial impact due to double handling and interim storage. This cost was not considered in the proposal and should be estimated before finalizing the final rule.

- It is doubtful that the nation's existing storage and distribution system can cope with the volume of product involved.

- Plants that now aggressively test product contact surfaces on a weekly basis, for example, could not justify shipping product if a positive result for *Listeria*-like or *Listeria* spp is reported. Thus, even for their own testing programs all product would have to be placed on hold when a product contact surface is sampled.

- The necessity to hold product will cause industry to test product contact surfaces at the minimum frequency specified in the regulation instead of the current, aggressive manner adopted by many establishments.

2) The proposal provides an alternative to testing that consists of including one or more CCPs in the HACCP plan for control of *L. monocytogenes* between lethality and packaging.

- This provision can be used to avoid testing product contact surfaces, a decision that would reduce consumer protection. In fact, the agency predicts that all large plants would establish CCPs in their HACCP plans.

- It is not possible to control contamination of exposed products between cooking and final packaging through the HACCP plan.

- Contamination of exposed cooked foods involves a wide variety of factors, all of which fall within the scope of SSOP and GMP (i.e., prerequisite programs). These programs are not amenable to CCPs.

- The agency's desire to force control of *L. monocytogenes* into HACCP is consistent with prior policies and reinforces the Agency's continued reluctance to recognize the importance of prerequisite programs in pathogen control.

3) It is assumed by FSIS that increased testing will lead to improved consumer protection.

- A significant data gap exists in the relationship between a product contact surface that tests positive for *Listeria*-like, *Listeria* species and *L. monocytogenes* whether the product will be positive and the risk to consumers.

- The proposal acknowledges the lack of data on the relationship between a positive surface and the extent to which a product will be positive, if at all. The proposal does not address whether a positive product contact surface or product will increase risk to consumers. No data are provided relating the level of contamination and the probability that multiplication to hazardous levels would occur before the product is consumed. There are no data to demonstrate the relationships that may exist under commercial conditions.

Even the information developed from epidemiological investigations is too limited to be of help.

- The agency has the data that can help answer some of these questions. For example, FSIS laboratory records can be reviewed for the number and percent of samples that show blackening in modified Fraser broth, yield *Listeria*-like colonies on MOX agar and subsequently confirm as *Listeria* species and *L. monocytogenes*.

- There have been numerous changes to FSIS policies since the late 1980's; yet, the data from the FSIS monitoring program through 2000, the latest available to interested stakeholders, show limited success. It is reasonable to question how this proposal will be more effective, result in lower frequencies of contamination for the different categories of products and result in improved consumer protection.

D. Lack of confidence that FSIS can provide the direction necessary to reduce the presence of L monocytogenes in food operations.

- Despite over 12 years of monitoring for *L. monocytogenes* in RTE meat and poultry products, FSIS lacks the expertise to provide guidance to those in industry who need the information necessary to minimize the presence of *L. monocytogenes* in product and the environment. FSIS should consider cooperating with industry to develop a scientifically based educational program that will provide the necessary guidance.

- The proposal indicates that guidance documents for the establishment of CCPs, sampling procedures and corrective actions will be provided with final action of the rule. This information is critical to industry's assessment of the proposed rule because the material will determine how the rule will be enforced. The proposed rule should not be finalized until after the guidance documents have been made available for review and comment.

- There has been great reluctance within the Agency to share helpful information with industry. For example,
  - it has been very difficult to obtain results from the FSIS monitoring program for *L. monocytogenes* in RTE foods.
  - information leading to outbreaks and cases has not been provided, so similar problems could be avoided by others in the industry.

- Data from the FSIS monitoring program could be used to measure:
  - industry's progress with regard to control on *L. monocytogenes*. When available, these data are incorporated into educational programs for industry to demonstrate trends and where continued improvement is needed. The data should be made available on a routine (e.g., semi-annual) basis and presented by product category.

- the effectiveness of the education programs sponsored by industry and, hopefully, by the agency.
- the effectiveness of FSIS regulatory policies.

- The trends for *L. monocytogenes* in the FSIS monitoring program should be evaluated to assess why certain categories show reductions while others do not. The trends, along with epidemiologic information, should be used to develop more targeted strategies that can lead to increased consumer protection.

E. Alternatives to the proposed rule for Listeria testing

- *Option 1* – retain the Directive issued in December, 2000:

  Since 1987, FSIS requirements have continued to be tightened, as new information became available. In December 2000, a new Directive (FSIS, 2000) that had been in development for about 2 years provided industry with 3 choices.

  During the past several years industry has been increasing its testing of the environment. This trend has been encouraged by workshops sponsored by the American Meat Institute and other trade associations to facilitate the transfer of experience and knowledge throughout the industry. There is now more genuine interest in environmental testing to aggressively assess the level of control, detect and correct problems and, thereby, improve consumer protection.

  Option 1 recognizes this favorable trend. By retaining the Directive and encouraging more testing through continued education, further reductions in exposure will occur.

  It is evident from the proposed rule that the Agency is not now prepared to evaluate the effectiveness of a sampling program or define the components of an acceptable program. The Directive would enable FSIS to become more familiar with environmental testing programs and determine what would constitute an acceptable, minimum testing program.

  Option 1 should involve a re-evaluation of the effectiveness of the Directive and education programs after 1 year to determine whether adjustments should be made to the Directive or if it should be replaced.

- *Option 2* – This option includes Option 1 and one modification to the Directive.

  The Directive specifies testing product on a monthly or quarterly basis. One of the many data gaps stated in the proposed rule is the relationship between a

positive product contact sample and the probability product will be contaminated.

Option 2 would involve sampling the product contact surfaces at the same time product samples are collected for analysis.

This option would generate the data needed to determine the relationship between a positive product contact surface and the probability that a product will be contaminated.

Since industry would place the product on hold, pending the test results, this modification would not increase the burden of hold and test beyond the frequency currently specified in the Directive.

Option 2 would address the primary concern expressed in the January 13, 2000, petition by the Center for Science in the Public Interest to the agency (CSPI, 2000). The total number of product samples analyzed annually would be dramatically increased over the approximately 3,500 samples mentioned in the petition. For example, an establishment with 3 HACCP plans for RTE products would be required to analyze 12 or 36 samples per year. The number of samples (12 or 36) would depend on whether the establishment sampled quarterly or monthly as specified in the Directive. The results from the product tests available for FSIS review.

- *Option 3* – Retain the Directive as in Options 1 and 2 and have FSIS sample the environment and/or products from establishments that do not implement a sampling program.

  Some establishments can not afford or, for other reasons, will not establish and maintain a sampling program for *Listeria*. The Agency should sample the environment and/or product from these establishments. This has been the policy in Canada for a number of years.

  This option would provide the Agency with the data and experience to develop the guidance documents mentioned in the proposal and promulgate meaningful regulations with a defined public health objective.

F. Regulatory policies should be changed to reflect the lack of risk associated with certain foods.

The proposal assumes all RTE meat and poultry products are of equal risk to consumers and contribute to burden of listeriosis. This is clearly not the case as is evident from the literature, epidemiological investigations, policies of other countries and the FDA/FSIS and FAO/WHO risk assessments (FAO/WHO, 2001; FDA-USDA, 2001).

A large variety of RTE meat and poultry products are of low risk because growth can not occur. For these products the proposed rule will not improve consumer protection.

Regulatory policies should reflect current scientific knowledge of the low risk associated with these foods.

A category should be established for low risk foods in which *L. monocytogenes* can not multiply due to low pH, low a_w, additives, or other reasons. The category should include products subjected to cook-in-bag/can technology, hot fill-and-hold processing, post-packaging pasteurization or fermentation/drying processes. The category should include frozen foods (e.g., frozen dinners) that are purchased frozen and reheated before serving.

This category of products should not subjected to testing, as is now the case, but should be required to meet a tolerance of 100 cfu/g as discussed below.

By establishing a new category for low risk products there would be increased awareness and incentive for industry to apply new technologies that can shift products of higher risk to the lower risk category.

G. A food safety objective should be established for L. monocytogenes of no greater than 100 cfu/g in RTE products at the time they are consumed.

Foods intended for higher risk populations should be required to meet more stringent standards (e.g., negative in 25g).

These recommendations would be in agreement with discussion documents currently before the Codex Committee on Food Hygiene that is chaired by the Dr. K. Wachsmuth, USDA, FSIS, OPHS.

Adopting a policy based on 100 cfu *L. monocytogenes*/g would be compatible with many of our major trading partners. The Canadian policy and the current proposed policy before the EU are just two examples.

The recent FAO/WHO risk assessment (FAO/WHO, 2001) indicates that this change would not result in a measurable change in risk. For example, if the entire food industry could meet an FSO of 100 cfu/g for the time all foods are consumed (and if a serving size of 100g is assumed) there would be about 25 cases of listeriosis per year, well below the estimate of 2130 cases.

The number of cases predicted if various criteria for CFU/serving could be realized at 100% effectiveness.

Maximum log dose at consumption (log CFU/serving)	Predicted No. of Cases
Baseline for all foods [a]	2130
4.5	24.9
3.5	5.3
2.5	1.1
1.5	0.2
0.5	0.06
-0.5	0.02
-1.5	0.01

[a] The number of predicted cases is based on distributions for *L. monocytogenes* provided in a previous table in the report.

The following text has been modified from the FAO/WHO report. *The entire report should be reviewed to understand the full context of the table and conclusions.*

Assuming 100% realization (i.e., compliance) of the above limits, the number of cases that would be anticipated was calculated. Calculations for the number of servings at dose values higher than that of the criterion being considered were added to the highest dose level. Thus, when a dose limit of 4.5 log was considered, the number of servings from the baseline data for 5.5, 6.5, and 7.5 log were added to the number of servings for 4.5 log. It is important to note that these values are in terms of CFU per serving. To calculate what this would be in terms of CFU per gram of food, the values in the table below would have to be divided by the serving size in terms of grams.

It is obvious from the table that eliminating the higher dose levels at the time of consumption has a large impact on the number of predicted cases, i.e., an approximate 99% reduction in cases could be potentially realized by implementing even the highest criterion (maximum log dose per serving = 4.5). However, it is important to note that this is based on cell numbers at time of consumption. Consideration of cell numbers at time of retail would have to be corrected to take into account the potential increases in *L. monocytogenes* that would occur as a result of growth in those foods that will support multiplication of *L. monocytogenes*. Likewise, this does not take into account the reality that there would likely be some incidence where the criteria would not be realized. Consideration of these factors requires a more rigorous evaluation of the risk posed, using more sophisticated modeling techniques. This advanced modeling was not completed in time for the expert consultation, but is anticipated shortly.

H. Additional information

Accompanying these comments is a manuscript, Control of *Listeria monocytogenes*

in the Food Processing Environment, that has been submitted for publication. The text contains additional information that is relevant to the proposed rule.

I. References

CSPI (Center for Science in the Public Interest). 2000. Petition for regulatory action to require microbial testing by industry for *Listeria monocytogenes* in ready-to-eat meat and poultry products. Submitted to the US department of Agriculture by the Center for Science in the Public Interest, Washington, DC.

FAO/WHO (Food and Agriculture Organization of the United Nations/World Health Organization). 2001. Joint FAO/WHO expert consultation on risk assessment of microbiological hazards in foods. Risk characterization of *Salmonella* spp. in eggs and broiler chickens and *Listeria monocytogenes* in ready-to-eat foods. FAO Headquarters, Rome, April 30 – May 4. Food and Agriculture Organization of the United Nations, Rome. To be available on both the FAO and WHO websites.

FDA-USDA. 2001. Draft assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. Center for Food Safety and Applied Nutrition, Food and Drug Administration, U. S. Department of Health and Human Services and the Food Safety and Inspection Service, U. S. Department of Agriculture, Washington, DC.

FSIS (Food Safety and Inspection Service). 2000. Microbial sampling of ready-to-eat (RTE) products. FSIS Directive 10,240.2, revision 1 (12/1/2000). US Department of Agriculture, Food Safety and Inspection Service, Washington, DC.

Mead, P. S., L. Slutsker, V. Dietz, L. F. McCaig, J. S. Bresee, C. Shapiro, P. M. Griffin and R. V. Tauxe. 1999. Food-related illness and death in the United States. Emerging Infect. Dis. 5:607-625.

Control of *Listeria monocytogenes* in the Food Processing Environment

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Abstract

The purpose of this paper is to provide guidance to food processors for controlling *Listeria monocytogenes* in food processing environments. Of greatest concern are outbreaks involving a few cases to several hundred cases scattered by time and location that involve an unusually virulent strain that has become established in the food processing environment and contaminates multiple lots of food over days or months of production. Risk is highest when growth occurs in the food before being consumed by the more susceptible population. This information forms the basis for establishing an environmental sampling program, organization and interpretation of the data and response to listeriae positive results. Results from such a program are provided, including examples of niches. Technologies and regulatory policies that can further enhance the safety of ready-to-eat foods are discussed.

Introduction

The purpose of this paper is to provide information that food processors and regulators can use as a basis for strategies for controlling *Listeria monocytogenes* in food processing environments. This paper also is intended as a supplement to two previous papers on listeriae control (83, 84). A portion of this material has been published (82). While the following is directed toward control of *L. monocytogenes*, some of the concepts can be applied for control of other pathogens (e.g., salmonellae) and spoilage microorganisms. When applying this information to other situations, the temperature of the environment in relation to the growth of the target organism should be considered. For example, salmonellae would not be expected among the resident flora of refrigerated workspaces.

The public health significance of listeriosis is well known. Although the disease may be rare (e.g., about 1 to 9 cases per million per year) and accounts for only about 0.02% of all foodborne illness, listeriosis accounts for about 28% of the deaths (8, 56, 76). This high degree of severity, particularly among those at higher risk (i.e., immunocompromised, neonates), emphasizes the necessity to manage their exposure. It also has been established that the foods of greatest concern are those in which *L. monocytogenes* can multiply. In general, foods that have been implicated in listeriosis have greater than 1000 CFU/g or ml (10, 40, 41). Consumer protection, then, largely depends on preventing contamination of those foods in which growth can occur.

Experience over the past 15 years points to recontamination as the primary source of *L. monocytogenes* in many commercially prepared ready-to-eat processed foods. This realization has led to significant changes in how the post-processing environment is managed (19, 83, 84). Major modifications have been necessary in plant layout and equipment design, procedures for

cleaning and disinfecting, and personnel practices. A realistic assessment is that *L. monocytogenes* will continue to be introduced into the environment where ready-to-eat foods are exposed for further processing and packaging. By controlling the establishment and multiplication of *L. monocytogenes* in these environments, it is possible to minimize, but not completely prevent, the risk of product contamination through the use of sanitation procedures.

Depending on the food and the environmental control program it should be possible in many food processes with a validated listericidal step (e.g., cooking), however, to control the prevalence of product contamination to less than 0.5%. If this can be achieved and assuming random distribution; then, at 0.5% there would be a 61% probability of accepting a production lot even if 100 samples were tested (43). Thus, end product testing becomes of little value for assessing and verifying control. Instead, the emphasis must be shifted toward environmental sampling as the best measure of control. An effective environmental sampling program has additional advantages when approached from a process control viewpoint. Ideally, the data can be used to detect trends indicating potential loss of control and enable timely corrective actions. The following will discuss the rationale for establishing an environmental sampling program, the concept of harborage sites or niches, how to organize and use data to detect sources of contamination, examples of niches, and possible future directions to enhance the safety of ready-to-eat foods.

Are all *L. monocytogenes* equally hazardous?

Variability in virulence within the species, *L. monocytogenes,* is slowly gaining recognition and acceptance. It has been confirmed through studies with mice that most, but not all, strains of *L. monocytogenes* can cause disease (7, 22, 37, 38, 67, 81). In preliminary studies with pregnant rhesus monkeys one strain previously linked to abortion in monkeys appeared to be more virulent among the 6 strains tested (Mary Alice Smith, Dept. Environ. Health Science, University of Georgia, personal communication). These and other studies (36, 45, 46, 64, 66, 69, 71, 88) show that some strains have greater potential for causing disease than others. This should not be unexpected since as can be seen in Table 1 a limited number of clones account for the majority of disease caused by other pathogens (66). Pathogenicity also is limited to certain types of *Yersinia enterocolitica* and *Escherichia coli* (42, 62, 89). *L. monocytogenes* has been categorized as "most strains are pathogenic, some strains may be pathogenic, some strains are non-pathogenic" (39). More recent research comparing different methods for assessing virulence has demonstrated that a plaque-forming assay using a HT-29 cell monolayer leads to three classifications: avirulent, hypovirulent, and fully virulent (71).

The virulence of *L. monocytogenes* is influenced by 6 genes on the chromosome in the PrfA-dependent virulence gene cluster and other important virulence genes (e.g., internalin genes) located outside the gene cluster (49). Presumably, strains having a full complement of virulence genes would have greater potential for causing disease. There also has been speculation that certain strains have greater potential to survive under adverse conditions and to multiply in the processing environment and/or in certain foods.

Additional evidence that certain strains are more likely to cause illness is that throughout the world three serotypes (i.e., 4b, 1/2a and 1/2b) account for 89-96% of human listeriosis (27). Of greater interest is the realization that a small number of clonal lineages have been responsible for

the large documented outbreaks in different regions of the world. For example, one epidemic clone of serovar 4b and a phagovar identical, or similar to, 2389:2425:3274:2671:47:108:340 has been confirmed by researchers using a variety of typing methods to have caused several major outbreaks (4, 5, 9, 18, 20, 26, 45, 51, 66, 79, 90), such as:

- Switzerland (1983-1987) - Soft cheese (Vacherin Mont d'Or); 122 cases, 34 deaths
- USA (1985) – Mexican-style cheese (Jalisco);142 cases, 48 deaths
- USA(1989) – unknown origin, (Philadelphia "outbreak"); isolates from 2 cases
- Denmark (1985-1987) – unknown origin; 35 cases,
- Denmark (1989-1990) – blue mold cheese
- France (1992) – pig tongue in jelly; 279 cases, including 22 abortions and 63 deaths

In addition, the same clone accounted for more than 25% of all human isolates in Sweden (25) and 20.7% of the isolates from patients and foods in Japan (60).

Two other genetically distinct clonal lineages were involved in outbreaks in North America (4, 18). One was the New England outbreak in 1983 (49 cases, 14 deaths) and the other was the frankfurter outbreak in 1998-1999 (101 cases, 21 deaths). Similar more highly virulent clonal lineages may occur among servars 1/2a and 1/2b.

Variability in virulence helps explain the low number of cases despite frequent exposure to foods containing *L. monocytogenes*. For example, the USDA-FSIS monitoring program for products sampled at FSIS inspected establishments between 1989 and 1999 has shown a prevalence rate for *L. monocytogenes* of ~ 2-3% for cooked beef, ~ 2-5% for small diameter sausages such as franks, ~ 1-3% for cooked poultry and ~ 1-5% for ready-to-eat meat and poultry salads. Sliced lunchmeat ranged between 4.2 and 7.8% between 1994 and 1999. In France, the prevalence rate for ready-to-eat foods decreased from 9 to 8 to 6% for the years 1997 through 1999 (17), indicating a favorable trend of continued reductions. Prevalence rates of 1-10% and higher are typical for a wide variety of foods throughout much of the world (27, 29, 30, 77); yet, symptomatic listeriosis remains a rare illness.

In summary, the information indicates that certain strains of *L. monocytogenes* are more highly virulent and much more likely to be involved in foodborne illness. This information helps food processors understand why the foods from one establishment have been implicated as a source of listeriosis and not the foods from other establishments, despite comparable rates of contamination. Virulence is but one important factor involved in the complex events leading to disease that must be taken into account when developing strategies for control of *L. monocytogenes*.

Resident and transient strains of *L. monocytogenes* in the processing environment

Another important piece of the puzzle involves studies on the microbial ecology of the food processing environment. Many researchers have demonstrated that certain strains of *L. monocytogenes* can become established in a food processing facility and remain as a member of the resident microbial flora for months or years. Table 2 summarizes many of the reports. In general, a variety of strains were detected in each food operation, particularly in the post-

processing environment, but certain strains were found during repeated visits to the establishment.

Experience in cold smoked fish operations indicates an array of strains in the receiving and raw fish handling area. As the fish is injected with brine and smoked other strains become dominant, even though these steps are not listericidal. Another shift can then occur during slicing (31).

Similar investigations have been conducted in other types of food operations but the data are inadequate to demonstrate whether a change occurs in dominant strains as foods are subjected to different conditions. The methodology used to differentiate the isolates has continued to evolve from serotyping or phage typing to more discriminating molecular-based methods. While the serotype(s) may have been reported and have been included in Table 2, newer DNA-based methods such as RAPD, PFGE and ribotyping are necessary to differentiate the strains recovered within each environment. These newer techniques provide much greater insight into the ecology of food operations and should provide guidance for improved control of *L. monocytogenes.*

It is significant that certain food operations have been known to harbor *L. monocytogenes* for long periods of time but the foods were not implicated in illness. Considering the continued detection of *L. monocytogenes* in a variety of foods, the existence of a resident flora of *L. monocytogenes* in food operations is more common than previously considered. The risk of listeriosis appears to be highest when a more highly virulent strain becomes established in an environment where ready-to-eat foods can become contaminated (e.g., between cooking and packaging) and growth occurs before being consumed by one or more members of the more susceptible population. While this might explain how outbreaks occur, industry and government must continue to treat all *L. monocytogenes* as potentially pathogenic.

Three scenarios leading to illness

To establish an affective environmental sampling program requires some understanding of the circumstances that lead to listeriosis. Foodborne listeriosis appears to generally follow a pattern of three scenarios.

- Scenario 1 consists of isolated cases for which information about the food is seldom available. The long incubation period (i.e., days to weeks) that can occur before symptoms develop makes it difficult to identify a specific food as the source (Table 3).
- Scenario 2 consists of an outbreak or cluster of cases involving a single lot of contaminated food. These events typically involve errors in food handling that lead to a food becoming contaminated and an opportunity for growth before the food is consumed. Once the implicated lot of food is no longer available further cases cease to occur (Table 4).
- Scenario 3 consists of outbreaks involving a few cases to several hundred cases scattered by time and location. The outbreaks typically involve an unusually virulent strain that has become established in the food processing environment and contaminates multiple lots of food over days or months of production (Table 5).

Experience gained from investigations of cooked meat and poultry operations indicates that a niche is commonly involved (Tables 2 and 6). A niche is a site within the manufacturing environment wherein *L. monocytogenes* becomes established and multiplies. The sites may be

impossible to reach and clean with normal cleaning and sanitizing procedures. In fact, in operations with an effective listeriae control program the processing environment typically appears clean and acceptable. The sites serve as a reservoir from which the pathogen is dispersed during operation and contaminates product contact surfaces and the food.

In all three scenarios, growth of *L. monocytogenes* occurs before the food is consumed. This information can be used as a rationale for establishing control systems that may be more effective for reducing consumer risk. Specifically, the systems should be designed to prevent scenario 3, recognizing that this effort should also minimize the risk of scenarios 1 and 2. A second priority is to comply with current regulatory policies, some of which may not be based on these considerations.

Significance of a niche

Microbiological testing of the processing environment and equipment is necessary to detect a niche. Examples of niches include hollow rollers on conveyors, cracked tubular support rods on equipment, the space between close fitting metal-to-metal or metal-to-plastic parts, worn or cracked rubber seals around doors, on-off valves and switches for equipment, and saturated insulation. Table 6 provides an extensive list of examples of sites that have been found to be the source of listeriae in commercial operations producing a wide variety of ready-to-eat meat and poultry products. It is significant that the source was often limited to very specific sites of growth that led to contamination of product contact surfaces during production. The location of the niche was typically limited to a specific packaging line (i.e., a number of pieces of equipment such as slicers, tables, conveyors, packaging machines used in series for packaging ready-to-eat foods). Parallel packaging lines located within a few feet of the positive line were consistently negative. This indicates that sampling plans should include all the packaging lines at a frequency that is adequate to detect loss of control. Furthermore, product being produced on packaging lines that are adjacent to a line that has tested positive should be considered acceptable as long as monitoring data support this assessment.

In some of the incidents, extensive sampling was necessary before the ultimate source(s) could be detected. Furthermore, the sources were often not detectable unless the equipment was operating and product was being produced. This creates a dilemma for which there is no ready solution. This means a significant time may elapse between when a problem is first detected and when the source is discovered. Additional time is then needed to make the necessary corrective actions to eliminate the source and verify the problem has been corrected. The time between when the first positive sample is detected and investigation of the source can be reduced by analyzing all routine monitoring samples individually rather than by compositing. However, analyzing all routine monitoring samples as individuals will significantly increase the analytical workload. This would be particularly burdensome for smaller operations. In some cases, prior experience may suggest certain equipment or sites as the source and where to apply corrective actions.

A rather commonly held opinion is that air is the source of contamination. Through 14 years of investigation to detect sources of contamination, the air in a room was never found to be a chronic source of contamination for product contact surfaces. Others have reported similar experiences (2, 44, 50, 79). Specific examples, however, can be cited where air from compressed

air lines has been implicated and has been traced to a niche near the point of use (e.g., growth in a filter) or air from an automated bag opener located under a table that was not properly cleaned and maintained. On one occasion, the exhaust from a small pump near the floor was an unexpected source. Experience also indicates that equipment placed too close to floor drains is more difficult to control, perhaps due to aerosols created during sanitation or air currents that may come from the drains as water levels change in the drainage system. This latter possibility is speculative and has not been confirmed by testing. Previous research that predates concern for *L. monocytogenes*, however, has demonstrated that floor drains can be a source of microorganisms to the immediate, surrounding air space (35).

Evidence indicates that construction in the vicinity where ready-to-eat products are exposed can increase the risk of product contamination. Some believe this is due to dust that is dispersed throughout the area. Such contamination may occur during the time of construction but of greater concern is the potential introduction of a new, more virulent strain of *L. monocytogenes* into the environment from an outside source or through disturbance of a harborage site (e. g., replacing floor drains, walls, cooling units). Should these strains become established in a niche in the ready-to-eat environment, then the potential for product contamination may increase. To address this concern, even greater attention is being given to separating construction zones from other areas where production continues to occur. In addition, the routine sampling program may be temporarily modified to verify that control is being maintained.

Six strategies for control of *L. monocytogenes*

If the preceding information is considered, then the basic components for a listeriae control program become clearer and include the following strategies:

- Prevent the establishment and growth of listeriae in a niche or other sites that can lead to contamination of ready-to-eat foods.
- Implement a sampling program that can assess in a timely manner whether the environment where ready-to-eat foods are exposed is under control.
- Respond to each positive product contact sample as rapidly and effectively as possible.
- Verify by follow-up sampling that the source has been detected and corrected.
- Provide a short term assessment (e.g., the last 7 samplings) to facilitate detecting problems and trends.
- Provide a longer term assessment (e.g., quarterly, annually) to detect widely scattered positives on a packaging line and to measure overall progress toward continuous improvement.

An earlier paper (84) provided guidelines to control listeriae in the environment where ready-to-eat foods are exposed. Some guidance also was provided on environmental testing (83, 84). This paper will provide further guidance on environmental testing and other information.

Environment and product contact surface testing

Two factors determine the effectiveness of a listeriae control program,

- the design of the environmental testing program and
- the response to a positive finding.

A routine environmental testing program is essential to provide a continuing assessment of control. In the event a positive product contact sample is detected, corrective actions should be initiated to identify and control the source of contamination, thereby minimizing the risk of product contamination. A wide variety of sampling schemes are used throughout the food industry. Experience has shown that the frequency of sampling the ready-to-eat environment in many operations should be at least weekly from each packaging line with emphasis on product contact surfaces (83). Where possible, the samples should be analyzed individually. In plants with few positive samples, however, compositing the sponge or gauze pad samples from each packaging line is an acceptable alternative. In addition, compositing may be necessary to minimize the cost impact to smaller operations.

Sampling frequency should depend on risk to consumers in the event the food becomes contaminated. Specifically, there should be little need for an extensive sampling program if

- it is known that contamination can not occur after a lethal treatment (e.g., canned or cook-in-bag products) or
- growth can not occur between when the food is produced and when it is consumed (e.g., frozen, dried, acidified or certain fermented foods).

Also, consideration must be given to how the food will be handled and prepared before it is consumed (40).

The data must be organized and reviewed as they become available. One method is to review the results for the previous 7 samplings to detect patterns and trends. Ideally, the results also should be reviewed annually, if not quarterly, to obtain a longer-term perspective and identify problems that might otherwise go undetected. While it would be preferable to analyze and control directly for *L. monocytogenes*, company policies may limit the analyses to *Listeria*-like colonies on modified MOX agar or colonies that have been confirmed to the genus, *Listeria*.

A successful sampling program will be aggressive with the intent to detect listeriae, if present. In addition, an effective listeriae control program must take account of the human element as well as the scientific basis for control. It is important to recognize that, even with an effective control program, extensive testing will periodically detect positive samples. This should be viewed as a "success" because the monitoring program has been effective, the problem can be corrected and consumer protection can be ensured. Recrimination against plant management for the presence of this ubiquitous bacterium invariably proves counter-productive in the long term. It is human nature to avoid problems and it is also fairly easy to generate negative results when testing for listeriae. In recognition of this important human element the best response is to provide sufficient technical assistance and laboratory support to help restore control. The information gained can be used to reduce, perhaps prevent, additional positives. Under the best of circumstances, sharing experiences with others can be very helpful.

For the reasons just stated, corporate and regulatory policies should encourage environmental sampling programs and consider positive findings more as a success of the monitoring program and less as a failure of control. A cooperative effort between industry and regulatory agencies would be more successful in preventing the likelihood of scenario 3 events and minimize the occurrence of scenarios 1 and 2.

Degree to which packaging lines can be controlled

Results in 10-12 plants producing a wide variety of ready-to-eat meat and poultry products indicate that listeriae can be controlled, but not eliminated, from the cooked product environment. For example, 50 to 68% of 79-106 packaging lines tested negative throughout the year when monitored weekly from 1990 through 1999. Another 20 to 29% of the lines had only one or two positive weekly samplings and 12 to 22% had three or more positives in the year. The routine methods employed throughout this time period were designed to detect *Listeria* species or *Listeria*-like, not *L. monocytogenes*.

Number of positive samples in a sample set

The number of samples that should be collected from a packaging line should be adequate to assess control. The number of product contact samples collected from each packaging line is fixed and ranges from 2 to 10 samples. The number selected reflects prior history of control and complexity of the system. In a few cases a list of up to 20 sites have been identified and the fixed number of samples are randomly collected each week from among the list. To provide information on the minimum number of samples that would be adequate to assess control, the data for one year from approximately 200 packaging lines were tabulated.

For the following discussion, a "sample set" consists of all the samples collected from a packaging line at one time. The number of samples collected from each packaging line was fixed. The number of samples found positive in the sample sets is summarized in Table 7. For example, for all the packaging lines with 6 samples collected each week, there were 33 instances when 1 of the 6 samples was positive, 8 instances when 2 of the 6 were positive and 5 instances when 3 of the 6 were positive. A positive consists of the presence of *Listeria*-like colonies on MOX agar plates.

For 117 (80.4%) sample sets, only 1 sample was positive from among the samples collected. On 19 (12.8%) occasions, 2 of the sample sites yielded a positive sample. For the remainder, the results indicate that on 8, 2 and 2 occasions there were 3, 4 or ≥ 5 positive samples. These data indicate that when listeriae were detected on product contact surfaces, the distribution normally was very limited and not widespread across the surfaces over which the product would come into contact. The data could be interpreted to suggest that increasing the number of sample sites would increase the probability of detecting listeriae within a sample set. There are limitations, however, to the number of samples that can be collected. Some packaging lines are lengthy and complex, while other lines consist of a single table for bulk packaging of the product into boxes. The cost impact also must be considered when establishing a routine monitoring program.

Frequency of repetitive weekly sample sets

Another factor to consider is the number of times a packaging line is found to be positive on consecutive samplings. The data in Table 8 summarize results for 2 years when 15,778 sample sets were collected from about 200 packaging lines producing a wide variety of products. On 731 (4.6%) occasions, a packaging line was positive for listeriae. On 483 (66.1%) of those occasions, the packaging line was positive on one week and negative the next (i.e., an isolated positive). On 136 (18.6%) occasions, a positive was detected from a packaging line on two consecutive weeks.

On 112 (15.3%) occasions, certain packaging lines were positive for 3 or more consecutive weeks. Again, the data indicate that when a positive packaging line is detected the degree of contamination is normally limited to an isolated positive or two consecutive positive findings. These events accounted for about 85% of the positive findings.

When the data in Tables 7 and 8 are considered together it is evident that listeriae positives are usually very limited in both distribution and frequency. One reason is that every positive finding is pursued to eliminate the contamination. This involves a variety of corrective actions and increased sampling beyond the basic monitoring program.

These data support a policy that in the event a positive product contact surface sample is detected, the initial emphasis should be in implementing corrective actions and not on product testing. If the initial corrective actions are not effective, then product testing becomes more appropriate. It is a matter of judgement whether product testing, which involves holding all the product produced from the positive line, should be applied after the first or the second positive finding. The data indicate a 33.9% probability that a line will again test positive on the next consecutive sampling.

Of greatest concern are lines with repetitive positives over a prolonged period of time. Some of these events reflect the difficulty in finding the source (i.e., niche). Hundreds of samples may be necessary to detect the source before effective corrective actions can be implemented. It is important that the monitoring program be capable of identifying these events, in particular, so appropriate safeguards (e.g., placing product on hold and test) can be implemented until the problem is resolved. At its best, a monitoring system will reveal the extent of a problem so that resources, that are typically limited, can be directed where the attention is most seriously needed.

The relationship between *Listeria* species and *L. monocytogenes*

What is the likelihood that a positive sample for *Listeria* species would confirm as *L. monocytogenes*? During 1990 and 1991, approximately 18,000 environmental samples were analyzed from 12 plants producing a variety of ready-to-eat meat and poultry products (83). It was found that 44% of the samples yielded black Frazer's modified broth, 15% yielded suspect colonies on MOX agar plates and 13% were determined to be *Listeria* species. Subsequent tests found that 40% of the samples with *Listeria* species were confirmed to contain *L. monocytogenes*.

The likelihood that a sample containing *Listeria* species would have *L. monocytogenes* varied with each plant (Table 9). During the years 1987-1991, the relationship remained relatively stable within each plant. Thus, the significance of a positive finding of *Listeria* species was highly dependent on the unique ecology characteristic of each plant.

Some advantages for testing only for *Listeria* species or *Listeria*-like compared with testing for *L. monocytogenes* are that the results become available sooner and at much lower cost. There is greater latitude in methodology. The concern that *L. innocua* or other species will mask the presence of *L. monocytogenes* is avoided. A program that is based on controlling *Listeria* species is more conservative and will control *L. monocytogenes*. It is important, however, to respond to all positive *Listeria* species results as though they are *L. monocytogenes*.

Seasonality

Experience has shown a higher prevalence rate in the processing environment during the summer months (83). This general pattern persisted for over 10 years with the degree of fluctuation being reduced through a process of continuous improvement, application of the recommendations previously reported and reduced response time to positive samples (82, 83, 84). The higher prevalence in the summer months was likely related to increased production and greater difficulty in maintaining control of the processing environment. A similar experience has been noted in the cold smoked fish industry with more positive samples being detected during periods of intensive production (e.g., in November -December) just before the holiday season (L. Gram, Danish Institute for Fisheries Research, Lyngby, personal communication). Thus, high throughput can be an important factor influencing control.

The above must be interpreted with caution. The relative influence of seasonality as a function of throughput, warmer temperatures and level of control may depend on the plant, the type of food being processed and other factors yet to be identified. For example, a low-throughput plant that is not in control would be more likely to yield a higher percent of positive environmental samples than a high-throughput plant that maintains an aggressive program of sampling and responding to the results.

Response to a positive finding

Experience has shown that the most effective response to a positive finding of listeriae on a product contact surface is to determine the source so it can be corrected. A simple map showing the layout of rooms and equipment can be beneficial. As positives are detected the sites should be marked on the map with the dates. A very simple schematic drawing such as appears in Figure 1 or a blueprint of the facility also can be used. By organizing the results to show which sites are more frequently positive and where they first occur, the source of contamination can be more easily located. In an environment that has been in control this will often lead to specific equipment that is harboring the bacterium. In general, contamination flows down along or through processing equipment with the flow of product.

When investigating the source of contamination an abbreviated analytical method for listeriae can be used. For example, it is faster and much cheaper to stop the analysis following incubation of the modified Frazer broth tubes. By striving for samples that do not yield black tubes, samples from more sites and different times during the day can be processed and more information can be obtained sooner.

When equipment has been identified as the likely source, the equipment should be dismantled (meanwhile sampling suspicious sites), cleaned and sanitized. This procedure is normally adequate and the preferred corrective action. Occasionally, extensive dismantling and cleaning will prove ineffective. For smaller equipment with many parts, cleaning in a re-circulating bath of hot water with detergent will be effective, particularly due to the heat. For larger equipment that can be moved, the sensitive electronics, oil and grease can be removed and the equipment

moved into an oven (e.g., smokehouse) for heating with moist heat. If this is not possible, the equipment can be covered with a heat resistant tarp and steam introduced from the bottom. When steam heating in an oven or under a tarp, the target is to achieve an internal temperature of 160°F (71°C) and hold for 20-30 min. Thermocouples placed within the equipment can be used to monitor the temperature.

Facing the reality that listeriae will continue to be introduced into the ready-to-eat environment

Despite best efforts, listeriae will continue to be re-introduced to food processing environments. Failure to control listeriae on the floors increases the likelihood that packaging lines will eventually test positive. One method to control listeriae on floors is to scrub the floors with caustic powder, rinse, sanitize with a high concentration of sanitizer (e.g., 800-1000 ppm quaternary ammonium compound) and dry. Maintaining clean, dry floors can be effective in most situations. A fine application of crystalline citric acid to maintain a pH of 4.5 or below when tested by pH paper can improve control in certain areas but the flooring material must be able to withstand this treatment. Other methods (e.g., frequent application of sanitizer) may prove necessary in areas where the floor remains wet due to the type of operation.

Cleaning and sanitizing procedures should be directed toward listeriae control. Cleaning more frequently (e.g., mid-shift, between shift) is counter-productive, detrimental to listeriae control and must be avoided. Maintaining a clean, dry environment during production is preferable to a wet environment. Contamination is normally limited to a single packaging line with adjacent lines not affected. Random contamination from air, people, packaging materials, etc is minor. In a facility with a controlled environment, growth within a niche is the major concern. It should be apparent that statements that listeriae contamination is due to poor sanitation indicates a lack of understanding of this difficult issue.

Extensive research has shown that bacteria adhering to surfaces in biofilms are more resistant to sanitizers. This may lead some to believe that biofilms are a key factor influencing listeriae survival and growth in the environment and on/in equipment. This may be a true in certain closed systems that rely on clean-in-place technology. In open systems, however, available chemical agents are very effective in removing listeriae, provided adequate mechanical action (e.g., scrubbing) is applied to the surfaces, and inactivated. Exposed surfaces, however, are seldom the source of listeriae. Of greater concern are enclosed areas (e.g., within a hollow roller on a conveyor) where food deposits and moisture accumulate and can not removed by normal cleaning, scrubbing and disinfecting. These harborage sites are not biofilms, per se, but rather niches where a variety of bacteria become established and multiply.

Future directions

Recognizing the continuing challenge and resources necessary to maintain control of the environment some future changes will occur. Continued improvements are needed in equipment design for ease of cleaning, to eliminate potential harborage sites and to minimize breakdowns and repairs during operation. There will likely be greater use of steam, as described above, for sanitizing certain equipment at some routine frequency (e.g., nightly, weekly). For this purpose, equipment must be designed so electronic parts can be easily dismantled. More durable floors are

needed to withstand the increased use of chemicals. Improved control is needed for re-circulating brine solutions for chilling foods (e.g., frankfurters, hams) after cooking. One method being evaluated is to acidify the brine solution to pH $\leq$ 3.5 with citric acid. There will be increased use of post packaging pasteurization when product quality will not be adversely affected.

New food additives that inhibit *L. monocytogenes* will be introduced and become more widely used in those foods where growth can occur. Current USDA-FSIS policies, however, provide few options for inhibiting *L. monocytogenes* in ready-to-eat meat and poultry products. The most widely used additives include sodium lactate, sodium diacetate, and combinations of the two (e.g., 2% sodium lactate on a dry weight basis and 0.1 – 0.15% sodium diacetate). Other methods (e.g., addition of peptides or live lactic acid bacteria cultures) are being investigated as additional means to prevent growth during refrigerated storage.

USDA-FSIS policy now requires adding a CCP when these new ingredients are added for control of listeriae. This requirement places an unnecessary burden on companies that use them to enhance consumer protection. Instead, their use should be encouraged. A CCP should not be required has been the case with other more traditional inhibitory additives such as salt, sodium nitrite, acidifiers, smoke.

Likewise, restrictive regulatory requirements for validating post pasteurization treatments that may not offer a 5 or 6D reduction should be avoided. Some processes may offer incremental protection that can be beneficial to enhancing consumer protection and their use should be encouraged.

One of the outcomes of the FAO/WHO risk assessment for *L. monocytogenes* in ready-to-eat foods is that risk increases with the number of cells consumed (28). Thus, consumer protection is not a presence/absence issue but rather a "number of cells consumed per serving" issue. While this may have been obvious to some, this information provides guidance to industry as it strives to minimize risk. To date, industry has been seeking technologies that prevent or eliminate the presence of *L. monocytogenes* in ready-to-eat foods but for some foods this is an unachievable goal. Industry should consider technologies that can minimize risk by reducing the likely number of cells consumed. This could be achieved, for example, through the use of additives that extend the lag phase but may not prevent eventual growth or post-packaging technologies that can significantly reduce but may not eliminate *L. monocytogenes* in a food. For certain products, until the ideal technology becomes available, combinations of partially effective control measures may be the preferred method to minimize risk while still offering products of acceptable quality. Admittedly, producers operating in a regulatory environment of zero presence for *L. monocytogenes* would still be in jeopardy if their product tests positive but the greater goal of consumer protection would be closer.

Categorizing foods according to risk to consumers; foods that do not support growth

Certain categories of food are of low risk to consumers because they do not support the growth of *L. monocytogenes*. Examples include foods with a low pH and/or a_w (e.g., barbecued products, fermented dry sausage, jerky, dry cured meats, precooked bacon) and frozen products that are typically heated before serving (e.g., frozen dinners, entrees, pizza). Many other categories of

products are of no apparent risk because they are cooked in the container in which they are sold or they are hot filled at a temperature that will preclude the presence of *L. monocytogenes*.

Regulatory policy should reflect these differences (40). Current FDA and USDA tolerances should be changed to recognize a food safety objective (FSO) of "no greater than 100 CFU/g at the time the food is consumed". This would recognize that low numbers of cells are less likely to be involved in foodborne listeriosis, the widespread distribution of *L. monocytogenes* in our environment and the difficulty of producing products that will consistently test negative for *L. monocytogenes*. It has been estimated that a regulatory policy based on an FSO of 100 CFU/g at the time the food is consumed would not reduce the level of consumer protection from a policy that requires absence in 25 or 50g (28).

The negative impact of a "zero presence" policy on efforts to control *L. monocytogenes*

Some additional explanation may be helpful for why industry would test for *Listeria* species or *Listeria*-like and not *L. monocytogenes*. The reason stems from the FDA and USDA-FSIS zero tolerance policy for *L. monocytogenes* in food and changing USDA-FSIS policies. Current FSIS policy requires recalling product in which *L. monocytogenes* has been found because the product is considered adulterated. The US policy for *L. monocytogenes* on ready-to-eat foods is more restrictive than in most other countries where tolerance levels have been established to reflect consumer risk.

Current USDA-FSIS policy also assumes that all product produced on a packaging line is adulterated if *L. monocytogenes* has been found on a product contact surface. The quantity of product implicated includes all product that has come into contact with the equipment from the previous clean-up until the next clean-up (i.e., clean-up to clean-up). In late 1998 a major recall of sliced lunch meats and franks totaling about 1.8 million pounds occurred after a plant's testing program detected *L. monocytogenes* on product contact surfaces. The product had not been linked to any known cases of listeriosis but subsequent testing by FSIS of products from retail outlets yielded *L. monocytogenes*. This event and many others since 1987 influenced the design and implementation of the environmental sampling programs adopted by industry.

A finding of *L. monocytogenes* in the cooked product environment also is considered evidence that the pathogen is "reasonably likely to occur" and, therefore, must be addressed in the HACCP plan. This creates a dilemma because control of post processing contamination is, in reality, controlled through prerequisite programs (84) and not through CCPs in the HACCP plan.

Finally, if product from an establishment is suspected of having been the source of human listeriosis, USDA-FSIS will obtain, through court order if necessary, all existing data from the establishment. This includes all environmental and product test results, any isolates recovered from the environment or product and maintained in a culture collection by the establishment for validation tests or other purposes and any PFGE files that may exist for isolates from the establishment.

The current regulatory policy is, in essence, a "zero presence" policy that does not encourage testing for *L. monocytogenes*, per se. Yet, there is general agreement on the importance of

maintaining an aggressive sampling program to assess control of the environment. At present, many industry programs represent a balance between providing maximum consumer protection and working with the constraints of regulatory policy. This has stymied research on the ecology of *L. monocytogenes* in the environment and led to the use of indicators.

Among the changes proposed by USDA-FSIS (33) is one to test for *L. monocytogenes* on all lots of product produced on equipment from which *Listeria* species or *Listeria*-like has been detected. This option has been debated within each company seeking to arrive at corporate policies that provide optimum consumer protection while still meeting their business requirements. To satisfy this proposal would require all the product produced on the day of sampling the product contact surfaces of equipment to be held in storage until the microbiological results are available and it is known whether the lot(s) can be released. According to the proposal, if subsequent testing of the product yields *L. monocytogenes*, then the lot(s) would be recalled from the market along with an accompanying public announcement. If adopted, this policy would shift the balance away from industry's desire to implement aggressive environmental testing programs, because industry would find it very difficult to hold all the product involved and also would frequently fail to meet shipping times expected by its customers.

The prevalence of positive product samples for *L. monocytogenes* detected by the USDA-FSIS monitoring program suggests the magnitude of the risk to industry as a whole, bearing in mind that many would be testing for an indicator (i.e., *Listeria* species or *Listeria*-like organisms). Thus, the 1-5% prevalence rate mentioned earlier for most products would be higher if an indicator is used. The impact of the proposed policy must be compared against the estimated reduction in cases of foodborne listeriosis below the current estimate of 2,493 cases per year in the U.S. (56). Very likely, greater consumer protection would result from establishing a policy that encourages frequent, aggressive testing for *Listeria* species or *Listeria*-like organisms, followed by appropriate corrective actions to positive results.

Clearly, regulatory policy has had a profound influence on industry's willingness to test for *L. monocytogenes*, per se, and generate the information needed to better understand the ecology of this potential pathogen in meat and poultry plants. In the year 2001, after more than a dozen years of regulatory control neither the agency nor industry has gained meaningful insight into the ecology of *L. monocytogenes* in the ready-to-eat meat and poultry product environment.

Additional information

A new book from the International Commission on Microbiological Specifications for Foods (43) provides additional guidance on sampling plans, environmental testing and the development of food safety management systems for control of microbiological hazards in foods. An excellent review of *L. monocytogenes* from Health Canada is available for additional information on this important pathogen (27). A risk evaluation and recommended control measures for cold smoked fish has become available (29).

In addition, two risk assessments on *L. monocytogenes* are nearing completion (28, 30). Both are available through the appropriate organization's website.

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Table 1. Numbers of clones of various bacterial species commonly causing disease (66).

Species	No. of clones identified	No. of clones commonly recovered from disease episodes	% disease caused by common clones
Bordetella bronchiseptica	21	3	87
Bordetella pertussis	2	2	100
Bordetella parapertussis	1	1	100
Hemophilus pleuropneumonia	32	2	47
Hemophilus influenza	182	9	81
Serotype b			
Yersinia ruckeri	4	1	89
Legionella pneumophila	50	5	52
Neisseria meningitis			
Serogroups B and C	192*	7*	85
Serogroup A	50	7	--
Shigella sonnei	1	1	100
Escherichia coli (neonatal invasive)	18*	5*	63
Salmonella spp (8 serotypes)	71	11	61-100

* Clone families composed of several or many very closely related clones

Table 5. Examples of scenario no. 3 outbreaks.

Country, year(s)	Implicated food	No. cases	Reference
France, 1975-76	Unknown	≤167	12
Switzerland, 1983-87	Cheese	122	5, 66
USA, 1985	Mexican-style cheese	142	51
Denmark, 1985-87	Unknown	35	32
UK, 1987-88	Pate'	>300	57
France, 1992	Jellied pork tongue	279	79
France, 1993	Pork rillettes	39	73
USA, 1994	Chocolate milk	53	21
France, 1995	Brie cheese	36	34, 72
Sweden, 1994-95	Cold smoked/gravad trout	6-8	26
USA, 1998-99	Franks (lunchmeat?)	~100	15
France, 1999-2000	Jellied pork tongue	26	24, 86
Finland, 1998-99	Butter	18	54, 55
USA, 2000	Cooked poultry	29	16
USA, 2000	Pate'	11	13

Figure 1. Example showing how positive results for samples collected from August 1 to 21 from 7 steps along a frankfurter line could be mapped.

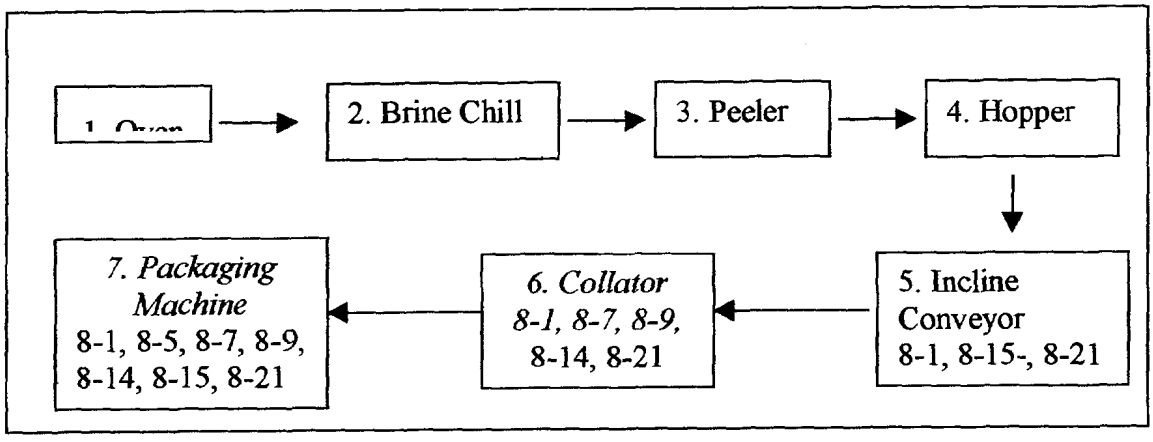

Table 7. Distribution of samples from product contact surfaces that tested positive for *Listeria*-like over a 1 year period. All samples were analyzed separately (i.e., not composited).

No. samples collected per packaging line	No. of sample sets with 1 to ≥7 positives						
	1	2	3	4	5	6	≥7
2	9						
3	19	1					
4	2	1					
5	28	3		1	1		
6	33	8	5				
≥7	26	6	3	1			1
Total	117	19	8	2	1	0	1
% of the total 148 positive sample sets	80.4	12.8	5.4	1.4	0.7	0	0.7

Table 8. Number and frequency of product contact surface sample sets that test positive for *Listeria*-like on consecutive weekly samplings, results from 2 years.

Total no. of sample sets collected and analyzed = 15,778 No. of sample sets testing positive = 731		
	No. of Positive sets	% of the positive sets
1 isolated positive	483	66.1
2 consecutive positives	136	18.6
3 consecutive positives	36	4.9
4 consecutive positives	32	4.4
≥ 5 consecutive positives	44	6.0

Table 9. Relationship between environmental samples that test positive for *Listeria* species and the presence of *L. monocytogenes*.

Plant	No. of positive *Listeria* samples	% of positive samples with *L. monocytogenes*
1	115	96
2	90	71
3	128	62
4	328	57
5	237	54
6	204	47
7	46	41
8	85	38
9	90	34
10	219	27
11	241	23
12	318	5

Table 2. Examples demonstrating that certain strains of *L. monocytogenes* can become established and persist in the environment of food operations.

Type of food plant	Time	Country	Implicated in illness?	Serotype	Reference
Goat cheese	11 months	UK	Yes	4b	3, 57
Cheese	4 years	Switzerland	Yes	4b	5
Cheese, blue veined	7 years	Sweden	No	3b	85
Ice cream	7 years	Finland	No	1/2	59
Smoked salmon	8 months	Norway	No	ND	74
Shrimp, raw shelled frozen	NS	Brazil	No	1, 4b	23
Trout/salmon, gravad	1 month	Sweden	No	4b	52
Smoked fish	Months	Switzerland	No	Several	91
Trout, gravad and cold smoked	11 months	Sweden	Yes (gravad)	4b	26
Smoked mussels	3 years	New Zealand	Yes	1/2	6
Smoked trout/gravad salmon	>4 years	Sweden	Possibly	1/2a	53
Smoked fish	14 months	Finland	No	1/2a (86%) 4b (14%)	47
Cold smoked trout	NS	Finland	No	1/2	2
Seafood, smoked salmon	Months-2 years	Norway	"Possibly"	4, 1	75
Smoked fish	Months	USA	No	ND	63
Cold smoked salmon	4 years	Denmark	No	ND	31

Paté from 1 plant was source of outbreak from 1987 to mid-1989	2 years	UK	Yes	4b(x); 4b	58, 65
Pork tongue in aspic – outbreak strain recovered from the implicated plant	Months	France	Yes	4b	79, 45
Cooked poultry	1 year	Ireland	No	1/2	50
Frankfurters	4 months	USA	Yes	1/2a	14, 87
Frankfurters - outbreak strain was not isolated from the plant when investigated	Months	USA	Yes	4b	15
Poultry, cooked deli products - outbreak strain matched a strain previously isolated from the same plant (87)	12 years	USA	Yes	4b	92

NS = not stated; ND = not determined

Table 3. Examples of isolated cases (i.e., scenario 1).

Type of food	Year	Country	Factors leading to case	Serotype	Reference
Raw milk	Early 1950s	Germany	Infant consumed milk from cow with Listerial mastitis	NS	Cited in 80
Frankfurter	1988	USA	Consumer with cancer ate 1 frank/day for lunch heated in the bun for 45 sec on high in a microwave oven.	1/2a	14, 87
Goat cheese	1988	UK	Normal healthy 40 year old woman consumed about 85g about 24 hours before onset of symptoms. Four packages from same lot had L. monocytogenes at 30 – 50 x 10^6/g. Elevated display case temperature may have been a factor.	4b	3, 57
Cooked chilled chicken purchased at a supermarket.	1988 (?)	UK	A 31 year old woman delivered a nonviable 23 week old fetus 5 days after eating leftover chicken held in the refrigerator for 3 days and then eaten cold on a salad.	4	93
Vegetable rennet	1988 (?)	UK	A 29 year old woman miscarried at about 23 weeks gestation. The bottle of rennet, held for 3 months in the refrigerator, was the only item to have the same isolate as the fetus.	4	93
Homemade sausage	1988 (?)	Italy	An apparently normal healthy man. Analysis of the remaining sausage yielded L. monocytogenes at 2.7 x 10^6/g. Sausage made from cooked pork stuffed into raw natural casing then held at 20-22C for 24 – 36 hours before eating.	4	11

Table 4. Examples of clusters of cases due to a single lot of food that typically has been mishandled permitting excessive growth of *L. monocytogenes* before the food is consumed (i. e., Scenario 2).

Type of food	Year	Country	Factors leading to cluster/outbreak	Reference
Coleslaw	1981	Canada	Cabbage fertilized with manure from sheep with listeriosis and held in cold storage for months, allowing possible growth before being used to make coleslaw.	80
Consumption of large amounts of shrimp, nonalcoholic beverages, Camembert cheese and cauliflower was significantly associated with illness. (?)	1989	USA	Ten of 36 persons attending a party developed listeriosis. Eating shrimp cooked by the club on the day of the party remained a significant risk factor after controlling for the consumption of other foods.	70
Rice salad	1993	Italy	Stored overnight at ambient temperature in June.	78
Chocolate milk (This outbreak also fits the definition of scenario 3 because other cases occurred and multiple lots of milk were involved)	1994	USA	Poor refrigeration after pasteurization. Temperature abused before serving at a July picnic.	21, 68
Corn and tuna salad	1997	Italy	A blend of canned corn and canned tuna prepared on May 20 was evidently contaminated during preparation. Subsequent tests suggest the time and temperature would have allowed growth.	1

Table 6. Examples of sources of *Listeria* species or *Listeria*-like contamination in ready-to-eat operations and corrective actions that were applied (1989-2000),

No.	Product	Equipment or area	Source(s) of contamination (i.e., niches or other sites of growth)	Corrective action(s)
1	Franks	Continuous brine chill chamber for product suspended from smoke sticks	Sponge rubber seals around edge of doors at top and side of chill unit	Removed rubber seals, redesigned doors so seals were not needed
2	Franks	Hopper that catches franks after peeling	Condensation from top of opening in wall between peeler room and packaging room	Sealed the cinder blocks to prevent moisture from accumulating in the blocks, installed stainless steel lip around top of opening to divert moisture down the side
3	Franks	Continuous brine chill chamber for product on racks with wheels	Doors made of rubber-coated fabric, large metal hinges extending the width of the door, and hollow bump guards at bottom of door	Replaced doors with rigid cleanable plastic material, large hinges and bump guards were removed
4	Franks	Ammonia unit used to chill the brine solution	Fiberglass insulation on ammonia line to brine chilling unit became saturated with brine splashing from the chilling unit	Removed contaminated insulation, cleaned and sanitized pipe and area, avoided placing insulation too close on pipe to the brine chiller
5	Franks	1. Refrigeration unit near ceiling of holding cooler before peeling	Condensation from the refrigeration unit	Refrigeration unit was cleaned and sanitized
		2. Area of brine chill exit and peeler	Hoses and spray nozzles at exit end of brine chill tunnel used to spray down franks for easier peeling	Replaced hoses and nozzles, initiated daily cleaning
6	Franks	Collator and conveyor	Undetermined	Covered with large tarp and injected steam

7	Franks	Peeler area	Overhead on/off valves for steam and water lines by peeler operator	Included in daily sanitation program
8	Franks and similar linked products	Peeler area (multiple events)	Peeler	Modified peelers for ease and effectiveness of cleaning, installed centralized casing removal systems so operator does not contact spent casings, built metal boxes with steam ports so peelers could be teamed each day before start of operation
9	Franks	Incline conveyor leading out of peeler room into packaging area.	Two ply Plexiglas shield guard on underside of conveyor had a crack where meat particles became entrapped	Plexiglas was replaced with a stainless steel guard.
10	Franks	Brine chill	Construction of brine chill tunnel had stainless steel framing with metal touching metal causing an uncleanable space	Modified framing for cleanability and to prevent material from getting into the space
11	Franks	Incline conveyor leading from the peeler room to the packaging area.	Contaminated liquid was discovered within a hollow split sprocket.	Sprocket was replaced with a solid sprocket.
12	Franks	Wall in peeler Room	Insulation behind fiberglass wall was contaminated by condensate from overhead pipe(s).	All fiberglas/insulation was removed from the wall. The concrete wall was cleaned with an acid base cleaner, sanitized, and sealed. The overhead pipes were re-routed to be closer to the floor.
13	Franks	Casing removal system (a long pipe through which vacuum conveys casings from the peeler to a canister in another room)	1. Design made it difficult to clean. 2. Inadequately cleaned and sanitized	1. Rebuilt system to shorten length, replace existing pipe with stainless steel, remove dead-ends and 90 degree angles. 2. Provided training and education to supervisor and person doing the cleaning

14	Sliced lunch meats	Slicer	Worn hydraulic seals at base of slicer, oil with water and product residue	Stripped slicer, cleaned and sanitized, placed into oven and applied moist heat, replaced seals, put on preventive maintenance schedule, used oil with listericidal additive (sodium benzoate)
15	Sliced ham from cans	Slicing/packaging line	Can opener with heavy wire safety cover	Modified cover so it could be removed daily for cleaning. OSHA had required that it not be removable for employee safety
16	Sliced pepperoni	Slicer	Build-up inside safety cover over gear and drive belt. Material from this site contaminated product conveyor located below	Changed cover so it could be removed for cleaning each night
17	Diced cooked meat or poultry	Dicer (multiple events)	Undetermined	Placed into oven and applied moist heat or covered with tarp and applied steam
18	Cooked sausage	Packaging machine	Crack in stainless steel covering on top edge of the packaging machine near loading area	Area cleaned, sanitized and welded
19	Cooked products	Conveyors (multiple events)	Hollow rollers	Replaced as detected. Where possible, replaced conveyors with sloping stainless steel slides
20	Hams	Brine chill tunnel for product on hanging racks	Damaged rubber seals on stainless steel door at exit end of tunnel	Replaced damaged door seals, modified cleaning procedure
21	Cooked turkey products	Conveyor between shrink tunnel and boxing	Worn conveyor made of rubber-coated fabric	Replaced conveyor with new material
22	Cooked turkey breast	Conveyor leading to packaging machine	Fabric conveyor belt material	Eliminated belt, changed to stainless steel slide

Chicken nuggets	1989	UK	52 year woman on steroids for lupus erythematosus. Upon investigation it was found that her healthy 29 year son had milder symptoms. Chicken from a take away shop was the assumed source, but this conclusion may have been influenced by a recently cited CDC case control study implicating undercooked chicken as a risk factor. Other foods were not mentioned.	1/2a	48
Sausage	1989	USA	94 year man with history of colon cancer. The sausage consisted of cooked pork, rice, etc stuffed into raw natural casing and sold in package labeled "Fully Cooked"	4b	95
Sliced lunch meat	1999	USA	Elderly man	NS	94

23	Cooked turkey breast	Cooked product stripping area	Hand held knives for opening product	Cleaned and sanitized daily in an automatic washer, knives not stored in lockers
24	Large cooked products	Bagging table	Air duct at base of table for blowing bags open	Modified table to make duct accessible for nightly cleaning
25	Breaded products	1.Exit conveyor from spiral freezer	Wheel bearings for conveyor belt	Removed and replaced wheel bearings
		2.Spiral freezer	Undetermined	Increased cleaning frequency and allowed equipment to defrost before cleaning
26	Cooked meat patties and links	Between freezer and packaging machine	Overhead conveyor	Provided safety ladder so conveyor could be cleaned from above rather than from below
27	Cooked meat patties and links	Wire mesh conveyor between oven and freezer	Hollow support rods for conveyor	Replaced with solid support rods
28	Cooked sausage links	Packaging machine	Stainless steel rods for pushing product into carton	Removed, cleaned, and sanitized push rods on daily basis

2706

September 5, 2001

Response of ConAgra Foods to the Proposed Rule on Chilling and Reheating Cooked Meat and Poultry Products

Summary and recommendations:

Incorrect scientific assumptions were made during development of the 1999 regulation for chilling of cooked meat and poultry products. In the absence of a valid, scientific basis for the current regulation, FSIS should conduct an evaluation of the risk associated with *C. perfringens* during chilling of cooked meat and poultry products in federally inspected establishments.

A brief review of the literature indicates that meat and poultry products have been frequently implicated in foodborne illness due to *C. perfringens*. The actual foods implicated, however, are often foods that contain meat and poultry as an ingredient.

The outbreaks are primarily due to improper temperature control following cooking at the foodservice level, schools and similar locations.

None of the reported outbreaks identified improper chilling of a cooked meat or poultry product in a processing establishment.

Cooked cured products have been rarely involved unless the method of food preparation led to a reduction in salt and nitrite content. The relative safety of cooked cured products is reflected in the limited, available published research and absence of sodium nitrite as a variable in predictive models. There has been no perceived need for extensive research on this food-pathogen combination.

With the possible exception of certain heavily spiced foods that have non-inhibitory levels of pH, a_w, etc, it is concluded that *C. perfringens is not a hazard that is reasonably likely to occur* and, therefore, need not be addressed in the HACCP plan.

Since *C. perfringens* is not a hazard that is reasonably likely to occur in the majority of perishable cooked meat and poultry products produced under federal inspection, the 1999 regulation should be revoked and the changes proposed on February 27, 2001, should not implemented.

Some level of control for chilling, however, should be specified in the interim to avoid egregious mishandling and the potential for production of spoiled, unsafe or unwholesome products. It is recommended that while the risk evaluation is being conducted the original guidelines issued in the May 1988 FSIS Directive 7110.3 should be applied.

The recommendation to use FSIS Directive 7110.3 as a basis for control of chilling is supported by 11 years of industry-wide experience in producing safe products under the Directive. The final target temperature for chilling should be 55F, the lower limit for growth of *C. perfringens,* and not a lower temperature (e.g., 40F).

Existing scientific data indicate that the time and temperature requirements originally established for chilling roast beef (formerly 9 CFR 318.17. h. 10. i.) can be applied to all cooked *noncured* meat and poultry products. We agree with the opinion expressed in the January 6, 1999 Federal Register notice:

> "Further, there is no reason why any of the cooling safe harbors for fully cooked and partially cooked products could not be used across product categories (whole, ground or comminuted), regardless of the species of origin of the tissue."

It is further recommended that investigational studies be conducted to determine if certain categories of product exist for which *C. perfringens* is a hazard that is likely to occur and more restrictive criteria should be established.

Where appropriate, a performance standard for chilling should consist of:

"no greater than a 3 log increase or no greater than 500/g
at the time the product is released for shipment".

The foregoing recommendations recognize the dilemma that when *C. perfringens* spores are inoculated into raw meat or poultry products and cooked in the laboratory the spores survive and, depending on the temperature profile during chilling and product composition, may multiply. This presents a situation where research indicates a public health need for a certain degree of control but experience indicates otherwise. It is the degree of control (i.e., rate of chilling) that is debatable.

FSIS has expressed the opinion that the risk of *C. perfringens* illness is best controlled through processes based on:

- Challenge tests
- Predictive modeling

These approaches to estimating risk have merit but they are not a replacement for other sources of information. A reality check that considers historical, commercial experience and a critical review of epidemiologic data is needed to place such research into perspective relative to risk.

FISI also has expressed the opinion that sampling product is an unreliable means to assess the safety and wholesomeness of products that do not meet the specified chilling requirements. We disagree and propose that in the event of a deviation, sampling a suspect lot is a valid option. The sampling plan and lot acceptance criteria should be:

> $n = 10$, $c = 3$, $m = 100$/g, $M = 500$/g for *C.perfringens* using the current method in the Compendium of Methods, BAM, or MLG.

The samples submitted for analysis should be refrigerated and not frozen, unless the product is frozen for normal distribution. In the latter case, packages or representative samples of the frozen product could be submitted for analysis.

The restrictions being imposed by FSIS for when cooked products are browned, smoked, caramelized, seared/charred, post pasteurized, etc, are unnecessary. have not been associated with increased risk and should be permitted as *before* the original guidelines were first issued. The assumption that exposure time during these processing steps should be added to the time for chilling the cooked products has not been demonstrated to increase risk. Furthermore, there are no epidemiologic data to warrant the restrictions that are being imposed by some FSIS personnel at the establishment level. These traditional practices have a long history of commercial use and had been considered safe until FSIS erred in its use of baseline data.

The no-growth requirement for *C. botulinum* is unrealistic and unnecessary. There have been no incidents of botulism in the United States due to poor chilling of cooked perishable meat or poultry products produced under federal or state inspection, including before requirements were established (Tompkin, 1980). In addition, there are too few laboratories in the United States to perform the necessary testing and, therefore, this requirement can not be verified.

If a target organism were to be selected for chilling, *C. perfringens* would be sufficient and more appropriate than *C. botulinum.*

It is evident from the background information (FSIS, 1998) and the regulation that followed in 1999 that FSIS considers 10^4/g as the upper limit for safe, wholesome non-adulterated product. Levels of 10^5/g and higher are unacceptable. We concur with this public health assessment. However, we do not believe traditional industry practices result in products having numbers anywhere near 10^4/g. Instead, we believe the number of *C. perfringens* in most cooked products is <1/g.

The current requirement of no greater than a 1 $\log_{10}$ increase in *C. perfringens* is unnecessarily restrictive and has led to the destruction of large quantities of safe, wholesome product. Even minor deviations from the chilling requirements have required extensive management and laboratory effort to demonstrate the products are safe, wholesome and not adulterated. The impact of an incorrect assessment or the destruction of questionable but safe, wholesome product was not considered in the development of the chilling regulation.

A closer review of the information provided during the process of establishing the performance standard in 1999 indicates the process was not transparent because certain important information was not available for review by the affected industry or general public. Information not available was the complete method for analyzing and confirming the presence and concentration of *C. perfringens* during the baseline line studies and the assumptions made relative to the quantity of product produced by an establishment.

CRPF has previously provided much of this information to FSIS in writing and at various meetings. The information also has been provided to our production facilities in support of their HACCP plans. Our establishments have complied with the intent of the regulation, but with some modification of the requirements and additional guidance material. Inspection personnel at various levels throughout the agency have been reluctant to accept "customized stabilization procedures" that differ from existing requirements, despite extensive documentation and supporting data. This is counter to the goal of providing flexibility to those who can substantiate the validity of alternative procedures. The reluctance to accept the scientific input from non-agency process authorities should be addressed by FSIS management, otherwise the potential value of alternative validated processes will not be realized.

The chilling regulation illustrates a need for change in the manner in which significant, science based regulations are developed. Consideration should be given to more in-depth public review and comment of the underlying science and assumptions upon which regulations are based.

This experience also demonstrates a general weakness in industry's ability to stay abreast of the numerous changes in regulations during the past 5 years and contribute meaningful sound, scientific information in a timely manner.

The following information is provided in support of these recommendations.

Part 1: Chilling

Background

On January 6, 1999 performance standards were finalized for cooking and chilling meat and poultry products in federally inspected establishments (9CFR318.17). This assessment of the regulation is concerned only with the stabilization (chilling) requirements and its supporting documents; namely:

Item A. Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper. FSIS, December 31, 1998.

Item B. Performance Standards for the Production of Certain Meat and Poultry Products. FSIS Directive 7111.1, 3-3-99.

Item C. Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization). Appendix B to Compliance Guidelines, Updated June 1999.

The performance standard for chilling states:

"There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than 1-$\log_{10}$ multiplication of *Clostridium perfringens*, within the product."

The scientific basis for the 1-$\log_{10}$ multiplication of *C. perfringens* is discussed in item A, above, and can be summarized as:

> Levels of about 10^6/g or greater are considered necessary for *C. perfringens* to cause foodborne illness.
>
> Thus, when investigating outbreaks CDC considers viable counts of *C. perfringens* of 10^5 or greater as a criterion for incriminating a food.
>
> "Data from the FSIS microbiological surveys indicate a "worst case" of approximately 10^4 (4 $\log_{10}$) per gram density of *Clostridium perfringens* on the raw product."
>
> "If cooling results in a 1 $\log_{10}$ relative growth of *Clostridium perfringens*, then there would be only a small percentage of samples with more than 5 $\log_{10}$ per gram density of *Clostridium perfringens* in the final product, but a non-significant number of samples with 6 $\log_{10}$ per gram density or more. Consequently FSIS is requiring that cooling processes that are used by establishment shall result in less than a theoretical 1 $\log_{10}$ relative growth of *Clostridium perfringens*."

The regulation and supporting documents actually specify two performance criteria for chilling. The first is stated, the second is implied from item A.

1. There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than 1-$\log_{10}$ multiplication of *Clostridium perfringens*, within the product.
2. The number of *C. perfringens* shall not exceed 10^5 per gram after chilling.

It is important to note that despite no evidence of risk to public health from the original May 1988 guideline (FSIS Directive 7110.3) the agency now considers it necessary to further tighten the chilling requirements because the original guidelines appeared to be too close to the edge. Even with the more restrictive requirements issued in June 1999 it was stated that there was little margin for safety with the required chilling times and temperatures.

CRPF Assessment

The statistical estimates and rationale provided in item A raise the question, why have there been no documented outbreaks of *C. perfringens* illness attributed to chilling cooked meat and poultry products in federally inspected establishments?

Considering the enormous quantity of cooked meat and poultry produced in the US over the past 30-40 years under various operating conditions and forms of inspection, there should have been numerous well-documented incidents. It is a certainty that substantial quantities of product would not have been chilled, for example, within the time-temperatures prescribed in FSIS Directive 7110.3 issued in May 1988.

The primary reason for the favorable record of safety with regard to *C. perfringens* (and *C. botulinum*) lies in the erroneous conclusion that high numbers of *C. perfringens* survive the cooking of meat and poultry products. The conclusion was based on "data" from the baseline studies:

- numbers of *C. perfringens* detected in raw meat and poultry.

  - It was assumed the numbers could be applied to cooked products.

- ignorance or disregard of the fact that only spores would survive cooking.

  - No confirmation, however, for the presence of spores was performed in the baseline studies.

- all the black colonies surrounded by a 2.4 mm opaque zone on the detection medium were assumed to be *C. perfringens*.

  - However, the method did not include confirmation for *C. perfringens*. Thus, the actual number of *C. perfringens* in the raw meat and poultry samples was not determined and can not be inferred from the baseline studies.

Thus, the "data" leading to the assumption of a worst case of 10^4/g of *C. perfringens* had no relevance to the number of *C. perfringens* that may be present in cooked product.

To the best we can determine the estimates for "*C. perfringens*" in raw ground products were influenced by the quantity of product produced by each establishment at the time of sampling. It is difficult to assess what this means to the subsequent calculations. It is unrealistic and statistically incorrect, however, to assume that a single sample collected from an establishment can be used to estimate the microbial content of all raw ground product emanating from an establishment at the time of sampling. The quantity of product should not have been a factor when analyzing the baseline results.

In retrospect, the process of establishing the performance standard in 1999 was not transparent because this aspect of the calculations was not available for review by the affected industry or general public.

The following data reported in item A indicate a high percentage of the samples actually were negative for colonies that would be considered presumptive, but not confirmed, for *C. perfringens*.

	Presumptive *C. perfringens* on TSC agar plates	
	No. Samples	% Negative
Raw ground beef	563	46.7
Raw ground pork	543	85.1
Raw ground chicken	285	49.4
Raw ground Turkey	296	71.9

Thus, there is a relatively low prevalence of *C. perfringens* in the raw meat and poultry used for further processing, even if it were assumed that the colonies were *C. perfringens*.

Information to help clarify the likelihood of *C. perfringens* in perishable cooked products

In 1964-65 we conducted an extensive survey for the U. S. Army Natick Laboratories involving 2,358 raw meat and poultry samples collected from slaughter establishments throughout the US and Canada (Greenberg et al, 1966). The samples were collected from Swift & Company plants throughout the US and Canada and intended to represent the worst case, being from the bloody neck area of beef and pork carcasses. The purpose of the survey was to determine the concentration of putrefactive anaerobic (PA) and *C. botulinum* spores in meat and poultry with the information being used to determine minimum radiation doses for shelf stability and safety. The data revealed that 77% of the samples had 3 or fewer PA spores per gram. The mean was 2.8 PA spores/g. The analytical method would have included *C. perfringens* in the count for putrefactive anaerobes. Since the survey was conducted almost 35 years ago, it is reasonable to assume the numbers would be lower today due to improved slaughtering conditions.

In response to the increasing concern by FSIS for the risk of *C. perfringens*, we initiated a survey in 1997 to determine the microbiological content of cooked ready-to-eat meat and poultry products after chilling. The samples consisted of both cured and noncured products from 7 establishments. Each plant submitted about 30 samples representing 3 pieces from each of 10 production lots. A core sample was removed from each product and analyzed for aerobic plate count and anaerobic plate count. From the products (ham, turkey, bologna, loaf items) we found:

No.	Aerobic Plate Count/g		
Samples	≤ 10/g	11-100/g	>100/g
184	151	25	7*

No. Samples	Anaerobic Plate Count/g ≤ 10/g	11-100/g	>100/g
184	172	11	1**

* highest aerobic plate count = 510/g
** highest anaerobic plate count = 1,800/g

It must not be assumed that the above numbers represent the spore population. Both aerobic and anaerobic spores would have been detected, if present. However, the meat, spices and other ingredients also contain certain heat resistant bacteria (e.g., lactobacilli) that do not form spores and can survive cooking. If present, *C. perfringens* would have been detected and enumerated in the anaerobic plate count.

In addition to the above, we have been analyzing product from chilling deviations. The extent of each deviation from the original FSIS cooling guidelines and subsequent 1999 regulation varied with each incident. The following data represent five years experience and a variety of products produced in establishments under FSIS inspection. The data support the premise that the number of *C. perfringens* surviving typical cooking procedures is well below the values assumed by FSIS in item A (FSIS, 1998). Unless otherwise stated, the analytical samples were core samples collected from the area of the product expected to receive the least amount of heat and the slowest rate of chill to below 55F, the minimum temperature for growth of *C. perfringens*.

Smoked sausage and franks (1995)	No. samples and results
Aerobic count	18 = <100, 2 = 100/g
Anaerobic count	19 = <10, 1 = 10/g

Cotto salami (1997)	
Aerobic count	9 = <10, 6 = ≤20/g
Anaerobic count	8 = <10, 7= ≤60/g

Deli loaf, cured (1998)	
Aerobic count	7 = <10, 3 = 20/g
Anaerobic count	9 = <10, 1 = 10/g

Bologna (1998)	
Aerobic count	1 = <10, 2 = ≤40/g
Anaerobic count	3 = <10/g

Turkey salami (1999)	
Aerobic count	9 = <10, 6 = ≤20/g
Anaerobic count	8 = <10, 7 = ≤60/g

Headcheese (1998)

Aerobic count	6 = ≤50/g
Anaerobic count	6 = <10/g
Clostridia	6 = <100/g

Ham (1995)

Aerobic count	20 = <100, 15 = 100, 1 = 200, 1= 600, 1 = 900/g
Anaerobic count	40 = ≤10/g

Ham (1995)

Aerobic count	7 = <10/g, 3 = 10/g
Anaerobic count	10 = <10/g

Ham (1995)

Aerobic count	4 = <10, 6 = ≤80/g
Anaerobic count	10 = <10/g

Ham (1996)

Aerobic count	6 = <10/g
Anaerobic count	6 = <10/g

Ham (1998)

Aerobic count	10 = <10/g
Anaerobic count	10 = <10/g

Ham (1999)

Aerobic count	12 = <10, 2 = <20/g
Anaerobic count	14 = <10

Luncheon meat (ham) (1999)

Aerobic count	15 = <10/g
Anaerobic count	13 = <10, 2 = 10/g
C. perfringens	15 = <10/g

Cured and noncured turkey products (1995)

Aerobic count	16 = <100, 1 = 100/g
Anaerobic count	17 = <10/g

Cured cooked turkey (1998a)

Aerobic count	3 = <10/g
Anaerobic count	3 = <10/g

Roast beef (1998b)

Aerobic count	10 = <10, 1 = 10/g
Anaerobic count	11 = <10/g

The 2 previous items (1998a and b) were cooked and chilled together

Roast beef (1998)

Aerobic count	2 = <10, 3 = <90, 1 = 950/g
Anaerobic count	6 = <10/g
Clostridia	6 = <100/g

Noncured cooked turkey (1996)

	Core	Surface
Aerobic count	10 = <10/g	10 = <10/g
Anaerobic count	9 = <10, 1 = 100/g	10 = <10/g

Noncured cooked turkey (1997)

Aerobic count	22 = <10, 1 = 10, 1 = 220/g
Anaerobic count	15 = <10, 7 = ≤60, 1 = 130, 1 = 1800/g

Noncured cooked turkey (1997)

Aerobic count	14 = <10/g
Anaerobic count	12 = <10, 2 = ≤20/g

Noncured cooked turkey (1998)

Aerobic count	7 = <10, 2 = ≤60/g
Anaerobic count	9 = <10/g
Clostridia	9 = <100/g

Noncured cooked turkey (1998)

Anaerobic count	7 = <10/g
C. perfringens	7 = <100/g

Noncured cooked turkey (1999)

Aerobic count	10 = <10, 4 = ≤60/g
Anaerobic count	14 = <10/g
C. perfringens	14 = <100/g

Noncured cooked turkey (1999)

Aerobic count	15 = <10/g
Anaerobic count	15 = <10/g
C. perfringens	15 = <100/g

Noncured cooked turkey (1999)

Aerobic count	8 = <10/g
C. perfringens	8 = <10/g

Noncured cooked turkey (1999)

Aerobic count	7 = <10, 1 = 10/g
C. perfringens	8 = <100/g

Noncured cooked turkey (2000)

Aerobic count	4 = <10, 6 = ≤40/g
C. perfringens	10 = <10/g

Noncured cooked turkey (2000)

Aerobic count	8 = <10, 2 = 10/g
C. perfringens	10 = <10/g

Noncured cooked turkey (2000)

Aerobic count	9 = <10, 1 = 20/g
C. perfringens	10 = <10/g

Noncured cooked turkey (2000)

Aerobic count	7 = <10, 3 = ≤20/g
C. perfringens	10 = <10/g

Noncured cooked turkey (2000)

Aerobic count	10 = <10/g
C. perfringens	10 = <10/g

Noncured cooked turkey (2000)

Aerobic count	10 = <10/g
C. perfringens	10 = <10/g

Cured cooked turkey (2000)

Aerobic count	5 = <10/g
C. perfringens	5 = <10/g

Cured cooked turkey (2000)

Aerobic count	2 = <10, 8 = ≤40/g
C. perfringens	10 = <10/g

Honey Ham (2000)

Aerobic count	7 = <10, 3 = ≤20/g
C. perfringens	10 = <10/g

Ham (2000)

Aerobic count	8 = <10, 2 = 10/g
C. perfringens	10 = <10/g

Deli loaf, cured (2000)

Aerobic count	12 = <10, 2 = ≤40/g
Anaerobic count	14 = <10/g
C. perfringens	14 = <10/g

Bologna (2000)

Aerobic count	2 = <10, 3 = ≤20/g
C. perfringens	5 = <10/g

Roast Beef (2000)

Aerobic count	5 = >10, 5 = ≤30/g
C. perfringens	10 = <10/g

Roast Beef (2000)

Aerobic count	4 = <10, 1 = 10/g
Anaerobic count	5 = <10/g
C. perfringens	5 = <10/g

Chili (2000)

Aerobic count	6 = <10, 1 = 20/g
Anaerobic count	5 = <10, 2 = 10/g
C. perfringens	7 = <10/g

Chili (2000)

Aerobic count	6 = ≤10, 2 = 120, 1 = 130, 1 = 160/g
Anaerobic count	6 = ≤10, 3 = ≤40, 1 = 110/g
C. perfringens	10 = <10/g

Chili (2000)

Aerobic count	3 = 10, 7 = ≤60/g,
Anaerobic count	7 = ≤10, 3 = ≤30/g
C. perfringens	10 = <10/g

Chili (2000)

Aerobic count	9 = <10, 1 = 10/g
Anaerobic count	2 = <10, 7 ≤30, 1 = 110/g
C. perfringens	10 = <10/g

Chili (2000)

Aerobic count	7 = <10, 2 = ≤20, 1 = 400/g
Anaerobic count	7 = <10, 2 = 20, 1 = 120/g
C. perfringens	10 = <10/g

BBQ chicken (2000)

Aerobic count	2 = <10, 7 = ≤40, 1 = 200/g
Anaerobic count	5 = <10, 5 = ≤90/g
C. perfringens	10 = <10/g

BBQ chicken (2000)

Aerobic count	3 = <10, 2 = 20, 1 = 110, 1 = 370, 1 = 1160, 1 = 2640/g
Anaerobic count	7 = <10, 2 = ≤20/g
C. perfringens	5 = <10, 2 = ≤20, 1 = 110, 1 = 140/g

BBQ chicken (2000)

Aerobic count	2 = 10, 4 = ≤50, 1 = 160, 1 = 910, 1 = 3,000, 1 = 8,000/g
Anaerobic count	3 = ≤10, 3 = ≤30, 1 = 250, 1 = 320, 1 = 2,320, 1 = 4,000/g
C. perfringens	10 = <10/g

BBQ beef (2000)

Aerobic count	10 = <10/g
Anaerobic count	3 = <10, 5 = ≤60, 1 = 390, 1 = 490/g
C. perfringens	10 = <10/g

BBQ (2000)

Aerobic count	1 = <1,000, 6 = 1,020 – 15,000/g
Anaerobic count	3 = ≤80, 1 = 120, 1 = 2040, 1 = 2130, 1 = 11040/g
C. perfringens	7 = <10/g

Cooked ground taco beef (2000)

Aerobic count	10 = 5,000 – 250,000/g (range)
Anaerobic count	1 = <10, 3 = ≤100, 1 = 220, 1 = 290, 1 = 430, 1 = 2440, 1 = 6000, 1 = 19000/g
C. perfringens	10 = <10/g

Cooked ground taco beef (2000)

Aerobic count	8 = <10, 2 = ≤20/g
Anaerobic count	4 = <10, 6 = ≤20/g
C. perfringens	10 = <10/g

Cooked ground taco beef (2000)

Aerobic count	1 = 950, 9 = 1,440 – 100,000/g
Anaerobic count	7 = 100 - <1,000, 1 = 1040, 1 = 1140, 1 = 1540/g
C. perfringens	10 = <10/g

Note: a number of the above lots were destroyed or reprocessed, depending on the information available.

A summary of the above data for raw meat and for products tested following a cooling deviation was recently presented at the annual meeting of the IAFP (Kalinowski et al, 2001).

As previously stated, it is normal to detect viable bacteria in fully cooked product. The population consists of heat resistant bacteria, some of which may be sporeformers.

The data show the prevalence and concentration of *C. perfringens* in cooked products is in reality very low, even in products that failed to meet the chilling requirements. The data also indicate that the products perceived to be of highest risk (noncured poultry, roast beef) were similar to the cured products and did not show evidence of growth of *C. perfringens* or other anaerobes.

The products of highest risk appear to be those that are heavily spiced, such as with taco seasoning. For these products consideration must be given to whether growth can occur. For example, heavily spiced foods that have a low pH or a_w would be of low risk due to the inherent inhibitory nature of the product.

Cooling deviations

Disposition of product(s) involved in a cooling deviation should be based on a review of all relevant information (e. g., times and temperatures, product composition, predictive modeling, microbiological tests, etc.).

The necessary information depends on the circumstances, the product, and the degree of confidence in making a correct decision with regard to product safety and wholesomeness. Examples of data that may be useful in making a decision include:

1. times and temperatures during chilling
2. % salt, % moisture, pH, a_w, etc.
3. phosphate, sodium lactate, sodium diacetate
4. sodium nitrite
5. laboratory analyses (e.g., microbiological results)
6. other relevant information that may influence the type of microorganisms that may be present and their expected rates of multiplication (Tompkin, 1986; Lücke and Roberts, 1993).

The following sampling plan and microbiological criteria may be applied to assess the safety and wholesomeness of the product:

$$n = 10,\ c = 3,\ m = 100/\text{g},\ M = 500/\text{g}$$ for *C. perfringens.*

Since high numbers (e.g., 10^6/g) of the pathogen are necessary for illness to occur, this and other appropriate sampling plans and criteria can provide an adequate margin of safety.

Products submitted for laboratory analysis must *not* be frozen prior to analysis, unless the product is normally frozen for distribution. The analytical method for *C. perfringens* should be selected from FSIS' MLG, FDA's BAM or the most recent edition of APHA's Compendium of Methods.

The use of microbiological testing to assess the safety, wholesomeness and adulteration of products following a deviation is provided for in Appendix B of the 1999 regulation.

We have found, however, that the agency generally disregards microbiological data when making its decisions on product disposition. The underlying reason is stated in the Appendix:

> "Because of a lack of information concerning the distribution of *C. perfringens* in product, sampling may not be the best recourse for determining the disposition of product following cooling deviations".

The compliance guideline suggests that greater credence can be placed on computer modeling for determining the disposition of product. We disagree. Both techniques can provide useful information and should be used to advantage. Microbiological sampling has the advantage by more accurately reflecting the effect of the characteristics of the product in question and the actual conditions to which the product was exposed. Furthermore, the data reflect the initial number of *C. perfringens* spores in the product after cooking and their ability to germinate and multiply.

The question of distribution of *C. perfringens* in the product can be addressed through the selection of an appropriate sampling plan such as those recommended by the International Commission on Microbiological Specifications for Foods (ICMSF, 1986). Although the 1986 ICMSF text is no longer available, an update of the principles for establishing microbiological criteria will appear in a new text (ICMSF, 2001).

Part 2: Reheating Cooked Product

In response to questions of food safety that might result when cooked products are reheated the following assessment and recommendations are provided.

There are various reasons why cooked products may be subjected to an additional heating step. Examples include 1)browning , 2)smoking, 3)caramelizing, 4)searing or char marking, 5)post pasteurizing, 6)as a corrective action following a cooking or chilling deviation, and 7)heating to reduce moisture content to bring products into compliance with specification or a regulation. The amount of heat applied in each case should be appropriate to achieve the intended purpose.

In the first 5 examples the heat is intentionally directed toward the surface of the product to achieve the desired effect. These processes are normally of short duration and cause a reduction in the microbial population on the surface of the product. The internal temperature may increase but this is incidental and of no consequence as the products are subsequently chilled. The first four examples have a long history of application with no evidence they have led to foodborne illness. The fifth example is intended to enhance the safety of packaged cooked products. More than 10 years experience with post pasteurizing roast beef has yielded favorable results with no evidence of increased risk from clostridial growth.

In the sixth example, the amount of heat that should be applied for corrective actions will vary with the deviation, the circumstances, existing data (including microbial data that

may have been generated), and input from various sources within USDA/FSIS. In general, for cooking deviations products would be reheated to the minimum internal temperature required for cooking. For chilling deviations a variety of options may be possible depending upon the information available to make a judgment of safety. For example, it may be possible to reheat a product to an internal temperature of 149F and hold for 2 minutes.

In the final example, relatively high temperatures are applied to drive off excess moisture from the product. Products that are reheated for moisture control will have been through a normal heating and chilling cycle and will have an internal temperature of 50F or below before reheating. Since the oven temperature is normally high (e.g., above 155F), the heating process will kill nonsporeforming bacteria that may be on the surface of the product. Thus, the concern becomes limited to the possibility of microbial growth within the product.

Four factors influence the likelihood of pathogen growth during reheating. They include the number of pathogen spores present in the product, time, temperature, and whether the product contains inhibitory ingredients. The pathogen of greatest concern in noncured products is *Clostridium perfringens.* Viable microbial counts within freshly cooked processed meat and poultry products are normally at 100 or fewer cells per gram. This is particularly so with poultry products that receive higher internal cook temperatures compared to many beef and pork products. The number of *C. perfringens*, if present, would make up only a small percentage of the population and would be less than 1/g.

It is important to note that *C. perfringens* can not multiply at temperatures above 122F or below 55F and multiplies very slowly at 55 to 70F. For example, in noncured turkey at 59F with 0.3% sodium phosphate and 1% salt, the USDA/ARS found a lag time of 59.6 hours before growth occurred and then, subsequently, the bacteria could double in number only every 6.6 hours. Extensive growth (e.g., to about 10^6/g) must occur in a food before *C. perfringens* illness will result.

In summary, after considering the low number of spores, the time required for their germination and outgrowth, the low internal temperature (i.e., 50F or below) of the product before reheating, and the presence of inhibitory ingredients (salt, phosphate, lactate and/or diacetate, nitrite), it can be concluded that the food safety risk can be controlled when cooked products are subjected to additional heating to reduce moisture content. It can be conservatively stated that exposure for up to 4 hours of reheating would not jeopardize the safety of these products. Thus, the following process conditions are recommended when reheating products to reduce the moisture content of cooked products:

-The internal temperature should not exceed 50F before the start of reheating. The initial internal temperature should be recorded.

-The oven temperature should be set for 155F or higher and recorded during the process.

-The time of reheating should be checked to confirm a process of 4 hours or less.

-The internal temperature of the product need not be monitored during the process.

-After reheating the product must be re-chilled as per normal procedure.

PART 3: HAZARD ANALYSIS FOR CHILLING PERISHABLE UNCURED AND CURED COOKED MEAT AND POULTRY PRODUCTS

Brief summary of epidemiologic information on the risk of *C. perfringens* in cooked meat and poultry products

There is an extensive history of foodborne illness associated with *C. perfringens* due to mishandling cooked foods containing meat and poultry at the foodservice level and, presumably, in the home. The following is from an extensive review of the literature in 1972 by Dr. F. L. Bryan, formerly Chief, Foodborne Disease Activity, CDC (Bryan, 1972).

" Meat and poultry products, particularly roast beef and turkey, are frequently incriminated as vehicles of *Clostridium perfringens* foodborne outbreaks (Table 1-*not included with this summary*). Such outbreaks are usually associated with foods prepared in food service establishments where large volumes of food are prepared several hours or a day or more in advance of serving and held during the intervening period at temperatures that are conducive to germination of spores and multiplication of vegetative cells. Typical outbreaks that have occurred in the United States are illustrated in Table 2" (*not included with this summary*).

"Factors, uncovered during epidemic investigations (and indicated in Table 2), that contribute to outbreaks of *C. perfringens* foodborne illness include failure to properly refrigerate cooked foods, holding foods at warm (bacteria incubating) temperatures, preparing foods a day or more in advance of serving, and inadequate reheating (Bryan, 1972). A summary of contributory factors involved in 59 outbreaks is illustrated in Table 3." (*Table 3 is not included with this summary*)

A review of the listing of 59 outbreaks in Table 2 of the publication shows all of the foods were noncured and most involved mixtures of meat with other ingredients (e.g., creamed turkey or chicken, gravy, meat pie, chicken salad). This information, along with other subsequent information, eventually led to the guidance material that was adopted in the Food Code for retail and foodservice establishments. Additional information on the underlying factors in foodborne illness between 1961 and 1976 is available in Bryan, 1978.

Between 1969 and 1979 there were 142 reported outbreaks attributed to *C. perfringens* in the US (Tompkin, 1983). *C. perfringens* foodborne illness accounted for about 23% of all outbreaks due to meat and poultry when the etiology was known. The data were tabulated from the CDC annual listings of outbreaks by vehicle and specific etiology. This indicates the significance of *C. perfringens* during that time but the CDC summaries do not provide the information necessary to assign the factors leading to the outbreaks.

CDC reported that between 1973 and 1987 there were 87 outbreaks attributed to meat and poultry products (Bean and Griffin, 1990). "Mexican foods", which tend to have a higher spice content, accounted for 23 outbreaks. CSPI using CDC data and other sources has listed 39 outbreaks attributed to *C. perfringens* since 1990 (CSPI, 2001).

For the period 1988-1992 the CDC reported 40 outbreaks in the US. The circumstances leading to the outbreaks were similar to the above. Fourteen of the outbreaks were attributed to meat and poultry while 8 were attributed to Mexican foods.

In the UK, which historically has had a high incidence of *C. perfringens* outbreaks, a total of 1,525 were reported between 1970 and 1996 (Brett and Gilbert, 1997). Three factors contributing to 93% of the outbreaks involved some aspect of inadequate temperature control after cooking; preparation too far in advance, inadequate cooling, storage at ambient temperatures. Meat and poultry products were implicated in 97% of the outbreaks. Large scale catering was the venue for 93% of the outbreaks.

The important role that foodservice plays in these outbreaks has been described by Dr. B. Hobbs (Hobbs, 1979). " In the United Kingdom and the United States, outbreaks occur throughout the year; there is no particular seasonal prevalence. They often follow meals prepared for large numbers of people in restaurants, schools, hospitals and factories; they also occur after banquets and meals prepared under crowded conditions for travelling coach parties." She also mentioned that "salted meats do not usually support the growth of *C. perfringens* unless the salt is diluted out during preparation."

Similar comments from Australia indicate that "most outbreaks have occurred in large eating establishments where large joints, roasts and batches of food are prepared and served. In addition to meat and poultry, stews and meat pies have been involved, and again the outbreaks have been associated with slow cooling after cooking and inadequate refrigeration." "The meat dishes are usually prepared in such a way that anaerobic conditions are provided for germination of the spores that survive cooking. Faulty cooling and storage may allow multiplication to 10^6/g or more from spores or post-cooking vegetative cell contamination. These conditions differ somewhat from those permitting staphylococcal food poisoning., where the vehicle is mostly cooked and cured meats, often recontaminated after cooking and eaten cold, the salt being inhibitory to *C. perfringens* but tolerated by staphylococci."

Why haven't outbreaks been traced to poor temperature control in federally inspected establishments? Certainly, the number of persons exposed to a "hazardous" lot would have led to recognition of a common source and the implicated lot of product. Many

factors may be involved in addition to the infrequent occurrence of *C. perfringens* spores in meat and poultry products.

One such factor may be due to the decline in viable vegetative cells during subsequent storage and distribution. Studies by Dr. Peter Bodnaruk in our laboratory have demonstrated that following growth in noncured cooked turkey at 108F there was a 1 $\log_{10}$ reduction in the number of *C. perfringens*/g after storage for 24 hours and greater than a 2 $\log_{10}$ reduction after 7 days (Bodnaruk, unpublished research). Considering the weeks that typically pass before cooked products reach the consumer, this could provide an additional protective effect. High numbers of cells (~ 6 $\log_{10}$ cfu/g) must be consumed for illness to occur.

Another such factor is likely due to the inhibitory composition of the product. Using cured cooked turkey as a test medium, the rate of growth of *C. perfringens* decreased as the salt concentration was increased from 1 to 2 to 3% (Kalinowski, unpublished research). At 3% no growth occurred through 6 hours at 110F, an optimal temperature for growth in this product. In another study the population decreased through 7 hours in cotto salami held at 110F. Since germination and growth of *C. perfringens* is highly dependent on product composition, it is expected that *C. perfringens* can not multiply in many of the cooked products produced under FSIS inspection during the times traditionally used for chilling or that may be occur in most temperature deviations.

It may be noted that many of the references for *C. perfringens* foodborne illness are old. This reflects the lack of research and Interest in this pathogen, the focus of interest having shifted to the newly emerging pathogens.

Noncured vs cured cooked meat and poultry

Noncured meat and poultry products such as roast beef, cooked turkey, gravy, stews, taco meat and a wide variety of other foods that are low in salt and do not contain sodium nitrite historically have been implicated in outbreaks of *C. perfringens* illness. From 1969 through 1979 noncured cooked meat and poultry and gravy accounted for 84% of the *C. perfringens* outbreaks in the US (Tompkin, 1983; Johnston and Tompkin, 1992).

Thus, the primary pathogen of concern in noncured products is *C. perfringens*. The temperature range for growth of *C. perfringens* is approximately 55–122F (ICMSF, 1996; Juneja, et al, 1996b; Labbe, 1989).

Contrary to information in the January 6, 1999 Federal Register notice, there is no evidence for growth above 122F. No growth of *C. perfringens* was observed over 3 weeks at 123.8F (Jujena et al, 1999). In another study one strain died at 120F while two others required 4-5 days for a 100-fold increase. At 124F all three strains rapidly died (Hall and Angelotti, 1965). The "Phoenix Phenomenon" described by Shoemaker and Pierson (1976) involved an injury-recovery process, not multiplication at 126F.

Research on the lower limits for the growth of *C. perfringens* in cook-in-bag turkey products indicate long periods of temperature abuse are required for germination and multiplication to unsafe levels. For example, Juneja and Marmer (1996) of the USDA/ARS conducted studies with ground turkey breast inoculated with *C. perfringens* and containing 0.3% sodium pyrophosphate and 0, 1, 2, and 3% salt. The product was cooked to 160F, chilled, then placed at 82.4F. Lag times (the time for adjustment of the cells before multiplication begins) for *C. perfringens* at 82.4 F for 0, 1, 2, and 3% salt were 7.3, 10.6, 11.6 and 8 hours respectively. Generation times (i.e., the time to double) ranged from 39.4 to 88.5 minutes for 0 and 3% salt, respectively. Additional research by Juneja et al., (1996) showed a lag phase of 2.27 hours at 107.6F in a broth medium with 1.5% salt and 0.15% sodium pyrophosphate.

From these data it is estimated that *C. perfringens* would not initiate multiplication for more than 2 hours at 107.6F and more than 7 hours at 82.4F in cooked noncured poultry products.

The data, the initial low number of spores in cooked product, and the fact that *C. perfringens* can not multiply below about 55F leads to a recommendation that noncured meat and poultry products conservatively can be safely chilled from 120 to 55F in 6 hours. This is the time and temperature specified in the May 1988 Directive 7110.3.

Outbreaks due to *C. perfringens* "are limited to cooked noncured meats, such as roast beef or turkey, as opposed to ham and other salted and cured meats" (Acuff, et al, 2001). The best explanation for this is very likely due to the combination of a low prevalence of *C. perfringens* spores in raw meat and poultry and the relative sensitivity of *C. perfringens* to the combined inhibitory effect of salt, sodium nitrite and other additives (Roberts and Derrick, 1978; Scott and Gombas, 1999).

If one looks hard enough, it is possible to find apparent exceptions to the above assessment. For example, several years ago a *C. perfringens* outbreak occurred in which corned beef was implicated. This unusual event was very likely due to cooking the raw corned beef in water before storage at an elevated temperature. During the cooking process, salt would have been leached from the product and the nitrite would have been reduced to a non-inhibitory level. Thus, the inhibitory system was reduced and *C. perfringens* growth was possible.

None of the predictive models from the US or UK include the effect of sodium nitrite on *C. perfringens* growth, the reason being that cured meats have not been involved in *C. perfringens* illness (T. A. Roberts, personal communication). Thus, it is not possible to estimate the risk associated with most cured products held at elevated temperatures.

There is evidence that cured products having a very low brine value (e.g., cooked cured turkey breast) are similar to cooked noncured turkey products. Challenge studies performed in our laboratory by R. Kalinowski and P. Bodnaruk (unpublished research) have shown no measurable inhibition of *C. perfringens* when compared to growth in a noncured control product when incubated in the range of 90-120F.

The foregoing information leads to the conclusion that *C. perfringens* illness is not reasonably likely to occur from cured cooked products.

An assessment of the risk associated with *Clostridium botulinum*

A similar conclusion can be reached for *Clostridium botulinum* but the severity of botulism warrants further consideration.

The temperature range for the proteolytic strains of *C. botulinum* is about 50 – 118F (ICMSF, 1996; Hauschild, 1989).

In contrast to *C. perfringens*, there have been numerous outbreaks of botulism throughout the world involving both cured and noncured meats (Tompkin, 1980). Thus, the potential risk of *C. botulinum* growth should be considered during the hazard analysis for a HACCP plan involving cured meat production, particularly since botulism can be life threatening.

Existing information indicates that the risk of botulinal germination and outgrowth during chilling is sufficiently low that it is not likely to occur. There is no record of an instance where failure to chill a commercially prepared cured product led to botulism in North America. With the possible exception of an unconfirmed outbreak involving ham three decades ago, cured products produced under USDA inspection have not been implicated in botulism.

Being an exceptionally heat resistant sporeformer, *C. botulinum* will survive cooking and given sufficient time at elevated temperatures can germinate and multiply. The relative risk of *C. botulinum* varies with the product composition (e. g., a_w, pH, inhibitor content). There are abundant data to explain the relative safety of these products but only two sets of data will be described.

The first set of data is based on predictions from the USDA/ARS Pathogen Model Program Version 5.1. This model has since been revised and updated but was originally developed for use as a tool in the development of HACCP plans and to assess the potential risk of foodborne illness under various conditions (e.g., when a deviation occurs). The model can be used to estimate the lag phase (i. e., number of days to initiate growth) when starting with 10 spores of proteolytic *C. botulinum* in broth at pH 6.2, adjusted for different brine levels, and stored at 59 to 93F, the upper and lower temperatures in the model. The brine values in cured products range from 2 (low salt products) to over 5%. A pH of 6.2 is typical of non-fermented or non-acidulated cured meats. It is important to note that the model does not predict the very significant antibotulinal effect that will result from the addition of sodium nitrite, sodium tripolyphosphate, and sodium erythorbate (Tompkin, 1993). Thus, the predictive values under estimate the extent of botulinal inhibition that exists in commercially cured products. Many products are formulated with 156 ppm sodium nitrite and the addition of sodium tripolyphosphate and sodium erythorbate.

Summary of data for *C. botulinum* from the USDA/ARS model program version 5.1:

% Brine	Temperature	Lag phase in "days to initiate growth" (confidence limits)	Pmax*
2.0	59F (15C)	37 (22 - 62)	0.18
2.5		45 (24 - 87)	0.09
3.0		50 (24 - 114)	0.01
3.5		outside model limits	
4.0		outside model limits	
2.0	68F (20C)	12 (9 - 17)	0.31
2.5		15 (10 - 23)	0.25
3.0		19 (11 - 33)	0.18
3.5		24 (11 - 54)	0.10
4.0		32 (10 - 98)	0.02
2.0	77F (25C)	6 (4 - 8)	0.42
2.5		7 (5 - 10)	0.38
3.0		9 (6 - 13)	0.34
3.5		11 (6 - 20)	0.29
4.0		14 (6 - 35)	0.24
2.0	86F (30C)	4 (3 - 5)	0.50
2.5		4 (3 - 6)	0.49
3.0		5 (4 - 8)	0.47
3.5		7 (4 - 12)	0.45
4.0		9 (4 - 19)	0.43
2.0	93F (34C)	3 (2 - 5)	0.54
2.5		4 (2 - 6)	0.55
3.0		5 (3 - 8)	0.56
3.5		6 (3 - 11)	0.56
4.0		8 (3 - 17)	0.56

*Pmax = maximum probability of growth or % of samples (i.e., broth tubes) with turbidity.

The USDA/ARS model does not predict growth for proteolytic *C. botulinum* below 59F, however, ICMSF book 5 (1996) which summarized the literature on this subject states that growth below 50F (10C) "has not been reported." "Hence, control of growth can be achieved by storage of foods at temperatures below 10C, irrespective of the pH value or water activity of the food."

The second set of data was developed in our laboratory prior to 1978 (Tompkin, 1978). The data consist of a series of 20 challenge tests in ham formulated with 156 ppm sodium nitrite and a brine level of about 3.75%. The products were inoculated with a pooled mixture of 5 type A and 5 type B botulinal spores to a target level of 100 spores/g. This spore level far exceeds that which may be expected under commercial conditions. If present, the level will likely be less than 1/g.

Each challenge test consisted of 25 cans of product placed at 81F after cooking and cooling to that temperature. Thus, a total of 500 cans of inoculated product were placed into incubation. Only 4 cans swelled before 40 days (i.e., 13, 15, 27, and 27 days). These data demonstrate that the time for botulinal outgrowth at ambient temperature in freshly cooked cured meats, such as ham, should be measured in days as a worst case, but weeks being more likely.

From the foregoing information it is evident that the risk of botulinal outgrowth during the chilling of cured meat and poultry products is exceptionally low. Furthermore, 50F can be used as the lower limit to ensure the safety of these products.

Consideration has been given to the potential for other microbiological hazards and it can be concluded that none are reasonably likely to occur during the time these products are being chilled from 50 to 40F. Thus, the time for products to chill from 50F to some desired lower temperature (e.g., for slicing or packaging) is important for product quality, not safety.

The above information indicates that a continuous chill from 120 to 50F in 20 hours would be sufficiently rapid to control *C. botulinum* in perishable cooked cured products.

Considering the margin of safety indicated from the above data, the unlikely occurrence of *C. botulinum* spores, and absence of botulism despite numerous instances of improper chilling throughout the industry during the past 50 years, it can be concluded that chilling cooked cured products need not be included as a CCP in the HACCP plans.

What can be learned from the above information?

Meat and poultry products frequently have been implicated in foodborne illness due to *C. perfringens*. The actual foods implicated, however, are often dishes that contain meat and poultry but summaries of reports of outbreaks in the US seldom provide this information.

The outbreaks are primarily due to improper temperature control following cooking at the foodservice level and similar locations. This is being addressed in the US through the Food Code.

None of the reported outbreaks identified improper chilling of a cooked meat or poultry product in a federally inspected processing establishment.

Cured, salted products have been rarely involved unless the method of food preparation led to a reduction in salt and nitrite content.

It can be concluded that chilling cooked cured products need not be included as a CCP in the HACCP plan for these products.

With the possible exception of certain heavily spiced foods that have non-inhibitory levels of pH, a_w, etc, it can be concluded that *C. perfringens is not a hazard that is reasonably likely to occur.*

References:

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2708

September 6, 2001

Response of ConAgra Foods to certain questions and concepts posed in the proposed rule

Page 12600, column 3, Meat patties – the idea that raw meat would be irradiated and then cooked in a commercial operation is not necessary. The advantage of a commercial operation is its ability to control the process and ensure a minimum thermal process.

A 5D thermal processing requirement will provide an acceptable and safe product. This is evident from the favorable record of safety since the 5D requirement was implemented.

Furthermore it is still unclear whether this proposal is intended to mean a 6.5 or 7D reduction in a 1g sample or 100g sample.

Page 12601, column 1 – the proposal to ensure there is no multiplication of *C. botulinum* is not necessary or feasible and the requirement of no greater than a 1 log increase in *C. perfringens* is not based on an accurate assessment of the risk associated with this pathogen.

Page 12601, column 3 – There is no need to establish a growth tolerance for *C. botulinum* and the proposed zero tolerance can not be verified.

Page 12602, column 1 – We agree that the microbial content of whole muscle products would be highest at the surface.

Page 12603, column 3 – see our comments in response to the proposed *L. monocytogenes* requirement.

Page 12604, columns 1, 2 and 3 - see our comments in response to the proposed *L. monocytogenes* requirement. Contamination of exposed RTE products can not be addressed through the HACCP plan. Also re-occurring positives for non- *L. monocytogenes* is not evidence of a serious sanitation problem. This indicates the likely presence of a niche. CCPs can not control contamination with *L. monocytogenes*.

The proposed "guidance to establishments" is a critical aspect of FSIS enforcement policy and should be made available so interested parties can comment before the rule is finalized. The same comment also applies to "FSIS will make available its directives to inspection personnel that will explain whether an establishment has implemented a testing regime sufficient to verify the efficacy of Sanitation SOPs in preventing direct product contamination by *L. monocytogenes* - - - -."

Page 12605, columns 1 and 2 – The issue of labeling is complex and requires considerable discussion before a policy can be developed.

Pages 12605–7 – The requirements for thermally processed commercially sterile products are in place and accepted by industry. There is no need to change the existing requirements.

Pages 12607-9 – The requirements for destruction of trichinae should be retained. As continued improvements in control of this parasite at the farm level occur the requirements should be re-evaluated. An option should available for using pork from suppliers with control programs in place that can ensure trichinae-free pork.

Page 12609, columns 2 and 3 - see our comments in response to the proposed *L. monocytogenes* requirement.

Page 12610, column 1 – It is not possible to apply a lower lethality than proposed until it is clear how the worst case is derived and what is meant by a lethality value. Is it based on 1g or 100g and how is the latter to be done?

" FSIS is unaware of any human health risk assessments that could be used to correlate changes in the performance standards with changes in public health benefits." This statement is an admission that the changes in the proposed lethality performance standards are not based on any information showing a public health need for change.

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September 6, 2001

Response of ConAgra Foods to the rule on cooking meat and poultry products

ConAgra Foods supports the use of science based performance criteria to define the expected outcome of the control measures applied at one or more steps in the food chain. Performance criteria can be used to communicate to industry the expected level of control but with flexibility in how the criteria will be met.

The cooking requirements in the current regulation and the proposed changes illustrate the importance of establishing a valid estimate of the initial concentration of pathogens in raw materials before a pathogen reduction step. This is important to arrive at regulations to ensure consumer protection and for when industry validates the effectiveness of its control measures. Thus, the comments that follow are as much concerned with the procedures used to arrive at the estimates for the initial pathogen level as with the proposed performance criteria.

The proposed changes in the performance standard for cooking are based on a statistical analysis of data from the baseline studies as discussed in the FSIS background document, Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper, December 31, 1998.

Recently, we requested assistance from a statistician to explain how the values for worst case were derived. Certain of the assumptions were obvious but it was not possible to follow through the logic through to the worst case.

We conclude that we can not effectively respond to the proposed rule in the absence of all the data used to arrive at the requirements and a clearer explanation of all the assumptions made in reaching the worst case scenario for all the species. This request for additional data and clarification must be fulfilled for this proposal to be a transparent process and so we can comment on it with a clearer understanding of its content.

As best we can determine,

It appears that the FSIS statistician has selected the highest reported concentration (e.g., 2,300/g for salmonellae in chicken) as a starting value. This means the agency has assumed that a product could be produced starting with 2,300 cfu salmonellae/g throughout a blend of product or, at least, at the site of slowest heating. The likelihood of this occurring is extremely low and was not considered in the estimate. For example, no consideration was given to the reality that under commercial conditions the sample unit containing 2,300/g would be reduced during mixing with lower count material, keeping in mind that all other samples yielded lower values and most tested negative.

The value was next inflated by selecting the upper bound confidence level associated with the MPN value.

It appears that since only one sample was tested from each lot, the analytical value was assumed to be the mean for the entire lot and, again, the upper bound confidence level was selected to arrive at the worst case. This is not clear and we are not certain that this was the case. If this were the case, it would be unrealistic and statistically unsound to assume that a single grab sample can represent an entire production lot.

Since the MPN determination necessitated analyzing the frozen retained aliquots, it was assumed that some cells died during frozen storage and the recovery rate was only 30%. This led to a further increase in the value.

The next assumption involved the loss of moisture (i.e., weight) that may occur in certain, but not all, products during cooking. The worst case estimate for raw poultry was 37,500 cfu/g or 5,362,500 cfu/143g. The worst case for beef was 720 cfu/g or 1,029,960 cfu/143g.

It appears that all the samples that tested negative for salmonellae in the baseline studies were disregarded, but this is not clearly stated. A common procedure for estimating initial numbers would be to assign a value to the negative samples and include them in the estimation.

The reports of the baseline studies state that some of the data were weighted according to the quantity of production. It is not known what this means or how this may have influenced the estimates, if at all.

An incorrect method was used to arrive at the 7D requirement

The worst case estimates and resulting performance criteria are in conflict with more than 70 years experience for establishing thermal processing criteria. Commercial thermal processes are based on the understanding that a D value is the time at a specified temperature that is necessary to achieve a 90% or 1 $\log_{10}$ reduction in the concentration of a target organism. This working definition assumes the target organism is located in the region of the food that receives the least amount of heat (i.e., slowest heating profile) and is based on a cfu/g.

The proposed rule is based on a worst case population in 143g and then specifies a D value to achieve a 6.5 or 7D reduction. This causes considerable confusion and makes it impossible to clearly understand what is being assumed and is being proposed. Specifically, two interpretations can be made from the information provided.

1. The D value assumes all the cells (i.e., 5,362,500 for raw ground chicken) are in 1 gram at the coldest spot in the product. If this were the assumption, then a 7D would be necessary to achieve the desired reduction.

2. If, however, the assumption is that the cells are distributed throughout the 143g then the concentration on a per gram basis would be 37,500/g. If this is correct, then a 5D would be necessary to achieve the desired reduction.

The second procedure will be found in textbooks that discuss how to arrive at an appropriate D value. We would agree with this approach and a required 5D process based on the available data,

commercial experience and information provided below, despite all the uncertainties of the proposal. We believe a 5D reduction is adequate to ensure that cooked meat and poultry products will be safe. For certain products, additional thermal processing may be necessary to achieve other desirable non-safety related attributes.

Since the proposal specifies 6.5 and 7D values, the possibility that the agency has assumed all the cells are in 1g that is located in the center or other colder region of the product must be considered.

Are the worst case estimates (e.g., 5.4 x 10^6 cfu/g for raw chicken) possible under current commercial conditions?

The agency admits that "the worst case levels in product are not expected to actually occur, provided products are handled appropriately before lethality treatments. The derived worst case levels are hypothetical constructs meant to represent upper limits of possibilities for raw product produced under appropriate, normal manufacturing conditions." (pp. 12595). We agree that the worst case levels are not expected to actually occur and question why the agency has insisted on pursuing a requirement that assumes otherwise.

Aside from the unreasonable assumptions made in the statistical analysis, the worst case results should have been subjected to a reality check including input from food microbiologists. For example, it is virtually impossible to have a concentration of salmonellae of $\geq 10^6$ cfu/g under commercial conditions without the raw material being spoiled.

To achieve such a level multiplication would be necessary. The lower limit for multiplication of salmonellae, the target organism, is about 45F, not 40F as mentioned on page 12575. At temperatures of $\leq$ 60F the normal spoilage flora associated with fresh meat and poultry would multiply much more rapidly and render the material unfit for use before such levels of salmonellae would be reached (Tompkin, 1996-copy attached).

It is unreasonable that consideration was not given to existing regulations, their enforcement or compliance and the probability of raw meat and poultry being held in a federally inspected facility in excess of 45F for the time necessary to achieve such a population.

The statistical analysis also did not consider the probability that the worst case population would be located in the region (e.g., center) of the product that is slowest to heat. The proposal does mention on page 12595 a concern that products should be processed "quickly before the raw product's surface temperature becomes elevated for sufficient amounts of time to allow *Salmonella* and other pathogenic organisms to multiply exponentially." We agree that time and temperature of holding raw materials before cooking is important for a variety of reasons, most of which have to do with quality. This statement, however, ignores the reality that the surface of the product will receive the highest amount of heat and that the temperature at the center of the product is of greatest concern for the destruction of enteric pathogens.

The worst case estimates also are based on baseline data developed before the full effect of the HACCP/Pathogen Reduction Rule was implemented. Thus, the baseline data very likely are not representative of current levels of salmonellae.

The procedure used to estimate initial levels of salmonellae in raw meat and poultry is critical to ensure food safety but the procedure should also avoid arriving at unrealistic criteria that adversely affect product quality. For example, if the estimate is unrealistically too high then the requirements would result in over-cooking, reduced consumer acceptance, excessive costs due to greater energy usage and, for some products, reduced production volume due to longer holding times.

Is there evidence indicating a need for more stringent performance criteria?

There have been very few instances of salmonellae surviving processes that have met federal inspection requirements during the past 40 years. Among the examples that could be cited include rare roast beef, cooked headcheese filled into raw animal casings and precooked beef patties. In each case the agency responded with new policies that defined the processing conditions necessary that would ensure consumer protection.

The FSIS monitoring program for salmonellae in cooked meat and poultry products provides evidence that existing requirements have been adequate to ensure consumer protection. We are confident that the positive findings in product have been due to post-process contamination and not due to salmonellae surviving cooking processes that were in compliance with regulations. The possible exception may have been during the initial period of transition to the newly imposed requirements for roast beef.

The 5D requirement for cooked beef patties resulted from a recommendation from the National Advisory Committee on Microbiological Criteria for Foods in response to an outbreak. Since the 5D requirement was implemented there have been no cases of illness attributed to the survival of salmonellae or *E. coli* O157:H7 in a product given the 5D cook. Is there new evidence that demonstrates the 5D is inadequate to ensure consumer protection, other than the estimates resulting from the worst case scenarios?

It is recommended that the procedure used to estimate the initial levels of pathogens in raw materials reviewed internally and then subjected to a critical analysis by another party (i.e., a peer review). Perhaps, the National Advisory Committee on Microbiological Criteria for Foods could assist in this capacity.

Finally, FSIS apparently has reached the conclusion that the existing cooking requirements are insufficiently stringent to provide adequate consumer protection. Yet, there has been no attempt to determine whether this conclusion is correct. Such an analysis should include a critical review of epidemiologic data to determine whether salmonellosis has been related to products produced under the existing regulations.

As a final comment on the proposed performance standards, colleagues from other countries have scoffed at the projected accuracy of the worst case determinations that have led to a 6.5D

kill being necessary for meat products while a 7D kill is needed for the safety of poultry products. Among food microbiologists the claim that this subtle difference in lethality (i.e., 6.5 vs 7D) is required for the safety of the two product categories has exposed a certain level of naivete and incredibility.

References

Tompkin, R.B. 1996. The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F. Presented during the Joint FSIS/FDA Conference on Time/Temperature. November 18, Washington, DC.

2708

September 6, 2001

Response of ConAgra Foods to the proposed lethality performance standard for fermented products

We prefer not to comment on the details of the assumptions made in arriving at the worst case level for *E. coli* O157:H7. Having participated in the development of the development of the original 5D lethality requirement we remain confident that this is adequate to ensure consumer protection.

The estimates for the concentration of *E. coli* O157:H7 in raw materials containing beef did not consider the fact that most fermented products contain a mixture of pork and beef, along with other ingredients. Furthermore, reported values for *E. coli* O157:H7 on carcasses or in ground beef would represent the highest values that are likely to occur. During processing the meat blend is ground one or more times and then mixed with salt, spices and other ingredients and blended. The mixture is then stuffed into casings. The net result is that considerable mixing and blending occurs that would reduce the likelihood of isolated, high concentrations of cells. Another factor is that *E. coli* O157:H7 dies slowest within the center of the product. Thus, with naturally contaminated meat the probability of the worst case population being within the center of the sausage is a factor that should be considered.

Since imposition of the 5D requirement, or its equivalent, there have been no reported cases of illness due to either E. coli O157:H7 or salmonellae in the US from products produced using the available options. There have been at least two episodes of illness in Canada attributed to dry sausage but those instances the manufacturers were not applying any of the options.

The options available for the manufacture of fermented products are all based on a 5D reduction in 1g rather than 100g. Thus, a validated process would involve demonstrating a reduction of *E. coli* O157:H7, for example, from an inoculum level of 10^6 cfu/g to 10^1 cfu/g.

We support the use of *E. coli* O157:H7 as the target organism in fermented products containing beef. Processes that are validated to achieve a 5D reduction of *E. coli* O157:H7 also should ensure the destruction of salmonellae. Thus, it should *not* be necessary to also validate the destruction of salmonellae.

On page 12600, columns 1 and 2 it is proposed that fermented RTE products that contain beef must be validated for both *E. coli* O157:H7 and salmonellae. This is not necessary to ensure food safety; imposes an unnecessary burden on producers, many of whom are smaller businesses; and there is no valid scientific justification. The proposed requirement is based on absence of a comparative study. Furthermore, it is not clear whether the 6.5 or 7 $\log_{10}$ reduction requirements are based on reductions for 1g or 100g (see above and our previous comments on lethality). This aspect of the proposed rule is very confusing!

We concur that there is no need to validate fermentation and drying processes for destruction of *Listeria monocytogenes*. The Philadelphia "outbreak" suggested that dry sausage may have been a source of listeriosis but this was early in the development of information of human listeriosis.

The investigators indicated there was no match between the products and the cases and this was subsequently confirmed by analysis of the isolates.

L709

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The significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F.

Presented during the Joint FSIS/FDA Conference on Time/Temperature
November 18, Washington, DC.

R. B. Tompkin, ConAgra Foods

Table 1. Minimum growth temperatures for selected foodborne pathogens.

	Minimum Growth Temperatures	
Salmonellae[1]	7C	44.6F
Pathogenic *E. coli*	7-8C	44.6-46.4F
L. monocytogenes	-0.4C	31.3F
Y. enterocolitica	-1.3C	29.7F
Campylobacter jejuni	32C	89.6F
Staphylococcus aureus	7C	44.6F
Bacillus cereus[2]		
psychrotrophic strains	4C	39.2F
Clostridium perfringens	12C	53.6F
Clostridium botulinum		
nonproteolytic	3.3C	38F
proteolytic	10C	50F

- [1]One report of initial growth on bacon at 5C but then the population decreased.
- [2]While growth of *B. cereus* occurs in milk at refrigeration temperatures (e.g., <7C), there is no evidence for this in meat and poultry. One study reported death of vegetative cells in ground beef at 12.5C (54.5F) and below.
- Parasites (e.g., *Trichinella spiralis, Taenia* spp., *Toxoplasma gondii*) and viruses do not multiply in meat or poultry products.

Source: International Commission on Microbiological Specifications for Foods. 1996. Microorganisms in Foods: Microbiological Specifications of Food Pathogens. Blackie Academic & Professional, New York.

Table 2. Estimated time (hours) for a ten fold increase at 50, 60 and 70F.

	Estimated Time (hours) to increase from 10 to 100 CFU/ml		
	50F (10C)	60F (15.6C)	70F (21.1C)
Salmonellae	107	24	9
E. coli O157:H7			
aerobic	50	21	9
anaerobic	123	38	16
L. monocytogenes			
aerobic	38	16	8
anaerobic	58	27	16
Y. enterocolitica	68	31	16

Source: USDA ARS Pathogen Modeling Program Version 4.0.

Conditions: broth medium, pH 6.0, salt 0.5%, sodium nitrite 0.0%

□

Table 3. Public health significance of meat and/or poultry held at 40-50F (4.4 to 10C) during storage and/or distribution.

Pathogen[1]	Estimated No. of cases of illness from meat/poultry[2]	Estimated cost/year (billion)[3]	Foods most likely to be involved[4]	Impact of 40-50F on growth of the pathogen[5]
T. gondii	2,056	2.7	raw pork	None. This parasite can not multiply in meat or poultry products.
Campylobacter	1,031,000-1,313,000	0.5 - 0.8	poultry	None. *C. jejuni/coli* can not multiply below about 90F.
S. aureus	756,000	0.6	cooked meat/poultry	None. *S. aureus* is a poor competitor and would not grow in raw meat or poultry at 50F or below. Most outbreaks involve cooked products that become contaminated and are held at 75-100F in the presence of air.
L. monocytogenes	808-837	0.1-0.2	ready-to-eat foods	Little, if any. Listeriosis has not been linked to raw meat or poultry . The potential for growth in some ready-to-eat foods does exist.
C. perfringens	50,000	0.1	cooked products	None. *C. perfringens* can not grow below about 54F

E. coli O157:H7	6,000 - 12,000	0.1-0.2	undercooked ground beef	Little, if any. The minimum temperature for growth is about 45F. At 50F, from 2 to 5 days would be needed for a 10 fold (1 log) increase depending on available oxygen
Salmonellae	549,000-2,745,000	0.3-2.6	undercooked meat/poultry	Little, if any. The minimum temperature for growth is about 45F. At 50F, about 4 days may be needed for a 10 fold (1 log) increase.

Source: [1,2,3] Department of Agriculture, FSIS, Proposed Rule. 1995. Federal Register 60: 6881-6881. (This source was used for "the pathogens," "estimated cases", and "estimated cost/year")

[4,5] The "foods most likely to be involved" and the "impact of 40-50F" are based upon the scientific literature.

Notes: • The Federal Register notice listed 50-75% of salmonellosis cases as being due to meat/poultry. The 75% value was used for the above estimate of cases.

• Recent estimates from the Center for Disease Control indicates the total number of cases of listeriosis is about 1100/year. Thus the number of cases from meat/poultry (50% of the total) now would be estimated at about 550/year.

□

Table 4. Estimated time (hours) for a one log increase of typical spoilage bacteria at 40, 50 and 57-59F. Applicable to raw meat and poultry.

	Estimated time (hours) to increase from 10 to 100 CFU/ml		
Isolate and strain #	39.2-41F (4-5C)	50F (10C)	57-59F (14-15C)
Pseudomonas (92)	39	18	8
Pseudomonas (69)	49	22	9
Ps. fluorescens	27	12	7
Ps. fluorescens (P-200)	-	13	7
Ps. fluorescens	22	-	-
Ps. fragi	17	9	-
Pseudomonas (21-3c)	24	11	7
Pseudomonas (1-3b)	23	9	8
Enterobacter aerogenes (Ps48)	40	14	7
Gram negative rod			
aerobic	14	-	-
anaerobic	32	-	-
Gram negative rod	25[1]	-	-
Achromobacter (7)	18	8	5
Achromobacter (438)	20	8	4
Achromobacter (5)	24	10	5
Pseudomonas (451)	32	13	4

[1] Data obtained at 6C.

Source: Adapted from Tompkin. 1973. Food Technol. 27(12):54-58.

Table 5. Effect of temperature on time of spoilage for pork and poultry.

	Temperature (F)	Days to spoilage
A. Chicken	32	18
	37	11
	42	8
	47	6
	68	2
B. Pork	31	14
	36	9
	41	5

Source: A. Adapted from Shannon and Stadelman. 1957. J. Poult. Sci. 36:121-123.
B. Unpublished data from Swift and Company (before 1977).

Table 6. Combined effect of temperature and bacterial content on time of spoilage of poultry and beef.

		Days to spoilage	
	Temperature (F)	Initial level of 100 CFU/cm²	Initial level of 100,000 CFU/cm²
A. Chicken	40	14	1 - 2
	50	6	1 - 2
B. Beef	32	22	11
	41	13	6
	50	8	4
	68	3	2

Source: A. Adapted from Ogilvy and Ayres. 1951. Food Technol. 5:97-102.
B. Adapted from Ayres. 1960. Food res. 25:1-18.

Table 7. Factors influencing the microbial content of ready-to-eat meat and poultry products from production through distribution/storage.

Factor	Measurement (s)
Ingredients	Types and levels of microorganisms in ingredients which can multiply and/or survive during subsequent processing, distribution and storage.
Formulating	The conditions of formulating and holding that may lead to microorganisms in finished product
Heating	The conditions of heating (e.g., time, temperature, humidity).
Cooling	The conditions of cooling and potential for recontamination.
Further processing	The conditions of holding and further processing before packaging
Product composition	Brine content / water activity Type and amount of fermentable carbohydrate Product pH; type and level of acidulant Level of smoke, liquid or natural Phosphate content Level of residual nitrite Hot oil dipping or flaming to brown the surface Spices, condiments applied to the surface after heating Sodium lactate content Metal ion content
Packaging	Product temperature during packaging and palletizing Degree of vacuumization and leaker formation Rate of oxygen transmission through packaging materials Addition of oxygen scavengers Modified atmosphere content
Contamination after heating	Types and levels of microorganisms contaminating the product between heating and packaging.
Distribution/storage	Time-temperature history after packaging. Damage to packaging permitting contamination

Source: Adapted from Tompkin, 1995. The use of HACCP for producing and distributing processed meat and poultry products. pp. 72-108. In A.M. Pearson and T.R. Dutson (eds.), HACCP in Meat, Poultry and Fish Processing. Blackie Academic & Professional, New York.

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Options for arriving at time, temperature criteria for chilling, storage and distribution of meat and poultry.

I. Chilling Rate

A. Carcasses, head meat, variety meats

1. Specify time and temperature requirements based upon:
   a. predictive modeling and published research
   b. data submitted by industry through conferences such as this and other means
   c. survey of current commercial practice for rates of chilling carcasses
   d. microbial sampling of carcasses before and after chilling
   e. review requirements from other countries

2. Arbitrarily establish a performance standard
   a. for example, <2 log increase in salmonellae and *E. coli* O157:H7

3. Conduct a risk assessment (This is highly recommended)

B. Cooked meat and poultry products

1. Provide time and temperature guidance such as in the current guideline (FSIS Directive 7110.3 Rev. 1; 1-24-89)

2. Establish a performance standard
   a. for example, <1.5 log increase in *C. perfringens*

II. Distribution/Storage

A. All perishable meat and poultry that requires refrigeration for food safety

1. a. Establish an action level in the range of 40 to 50F because a critical limit based solely upon temperature does not exist in this range. A valid critical limit would have to specify time and temperature.
   b. A temperature of 45 or 46F (7 or 8C) is suggested.