



January 27, 2012

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
FSIS Docket Room
1400 Independence Avenue, SW
Patriots Plaza 3
Mailstop 3782
Room 163A
Washington, DC 20250-3700

RE: FSIS-2011-0014 - Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information

To whom it may concern:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, veal, and a majority of the turkey produced in the United States.

Consumer health is a driving force in the production of meat and poultry products. The meat and poultry industry is committed not only to improving the safety of meat and poultry products, but also to offering diverse nutritional products to consumers so they can make an educated decision in choosing the food that best fits their personal lifestyle and family needs.

AMI supports voluntary sodium reduction initiatives that do not compromise the food safety of meat and poultry products. The following comments address specific concerns that require further clarification and/or additional consideration by the Department of Agriculture's Food Safety and Inspection Service (USDA FSIS) and Department Health and Human Services' Food and Drug Administration (HHS FDA).

Sodium Reduction Initiatives Should Remain Voluntary

Sodium reduction initiatives should be voluntary and designed in cooperation with the food industry to best achieve practical and meaningful strategies through the use of sound science. A “one size fits all” approach would not work because of the complexity of uses of sodium in food products, especially in the safety of meat products. AMI is willing to work with FSIS and FDA, if after review of the scientific evidence and stakeholders comments, the agencies determine it is necessary to develop voluntary initiatives.

Sodium and Sodium Compounds Have an Important Role in Meat and Poultry Safety

Salt, or sodium chloride, plays a critical role in the production of meat products – whether used by large commercial processors, local butchers, or even within the consumer’s home – to improve the flavor, texture, and safety of those products. Reducing sodium is not as simple as adding less and sending the product to market. The meat and poultry industry must ensure that there are no unintended food safety consequences to product reformulation, while still meeting consumer flavor and quality expectations.

Salt or sodium chloride’s role as a preservative and food safety ingredient is one aspect of a multi-hurdle approach toward maintaining the safety of products. In the last 20 years, the meat and poultry industry has also learned in more quantitative fashion the importance of sodium chloride in managing of pathogenic bacterial risks presented by *Listeria monocytogenes*, *Salmonella*, and pathogenic *Escherichia coli* in meat and poultry items.

L. monocytogenes is of particular concern in ready-to-eat processed meat and poultry items because it is very difficult to eradicate from the environment and if products are contaminated, the organism will survive and grow (even at refrigerated temperatures) unless growth inhibitor systems are used. Three common ingredients used for this purpose are sodium chloride, sodium or potassium lactate, and sodium diacetate. These inhibitors are used in up to 70 percent of processed items in the U.S. marketplace. Reduction in the use of one requires a concomitant increase in another in order to maintain the same degree of safety. Alternatives to these ingredient approaches exist, but are not widespread due to ease of use, economic, and product quality issues - specifically loss of consumer acceptance for flavor, decreased shelf-life, and loss of myofibrillar functionality, among others.

As mentioned above, a critical role of sodium and sodium compounds in meat and poultry products is food safety and preservation, with additional benefits of improving product palatability. Taormina has eloquently summarized the critical food safety necessity of sodium chloride in the production of food products in his article “Implications of Salt and Sodium Reduction on Microbial Food Safety” in *Critical Reviews in Food Science and Nutrition*.¹ Taormina concluded:

*“...sufficient research has not been conducted to remove and/or reduce NaCl in processed and restaurant foods to the extent being proposed by various stakeholders through biomedical journals and other media. Governments and food protection groups must convene to weigh the societal risks versus benefits and potential economic burdens associated with imposing further restrictions on use of NaCl in food formulations. Epidemiological and clinical evidence indicates that long-term public health benefits would result from reducing NaCl in human diets. However, short-term unintended consequences related to the impact on microorganisms have not been fully explored. Regulatory action on reducing NaCl in foods without first obtaining thorough predictions on the behavior of foodborne pathogens and spoilage organisms in the food supply could lead to significant disruptions to international food commerce at best. These disruptions would be caused by microbial survival, growth, and spoilage when and where previously unexpected using processing and distribution parameters developed for the current amounts of sodium in foods. **At worst, a rush to significantly reduce NaCl without research and careful planning could lead to significant increase in exposure of humans to foodborne pathogens.**” (Emphasis added)*

AMI also encourages FSIS and FDA to consider the work of Doyle and Glass, who published “Sodium Reduction and Its Effect on Food Safety, Food Quality, and Human Health” in the *Comprehensive Reviews in Food Science and Food Safety*.² The Doyle and Glass review considers the published data on the effect of excess salt consumption on health, the functionality of sodium chloride in the production of processed foods, and possible reformulation strategies for sodium reduction while maintaining critical food safety standards.

¹ Taormina, P. 2010. Implications of Salt and Sodium Reduction on Microbial Food Safety. *Critical Reviews in Food Science and Nutrition*. 50(3): 209-227. DOI: 10.1080/10408391003626207. <http://dx.doi.org/10.1080/10408391003626207>.

² Doyle, M; Glass, K. 2010. Sodium Reduction and Its Effect on Food Safety, Food Quality, and Human Health. *Comprehensive Reviews in Food Science and Food Safety*. 9(1):44-56. DOI: 10.1111/j.1541-4337.2009.00096. <http://www3.interscience.wiley.com/journal/123221587/abstract>.

Sodium nitrite is an additional sodium compound commonly used in the production of meat and poultry products. Sindelar and Milkowski succinctly summarized the function of sodium nitrite in improving the quality and safety profile in cured meat and poultry products. The addition of sodium nitrite has *“been shown to be an effective antimicrobial with bacteriostatic activity, its usage is clearly a benefit to both industry and consumers. ...the effect in the control of C. botulinum is indisputable and well documented. ...botulism has been completely controlled by nitrite use in cured meat products.”*³ Challenges to removing sodium nitrite from meat and poultry products would include but are not limited to: an increase in finished product cost; considerable increase of consumer dissatisfaction; increased challenges to control microbial growth; and the identification of an ingredient that would provide the same quality and safety characteristics without representing a health hazard.⁴

The examples in Appendix A demonstrate the changes in microbial growth that must be thoughtfully considered before any sodium or sodium compounds reduction reformulation occurs. Reducing salt and sodium requires modifications to other food safety ingredients and processes, and it takes time to balance the food safety, texture, flavor, and cost implications of these modifications.

For the foregoing reasons, with respect to the decision-making process in development of sodium reduction recommendations, AMI respectfully requests that FSIS and FDA consider the possible unforeseen food safety consequences of such recommendations.

Sodium in Functionality and Quality of Meat and Poultry Products

The functionality of sodium and sodium compounds when added to muscle tissues will affect the quality of the meat and poultry product. Sodium in the form of sodium chloride is the primary source of added sodium to meat and poultry products. Sodium phosphates, sodium nitrite, sodium lactate, among others are all sodium compounds used by the meat and poultry industry in developing their products. Compounds such as sodium chloride have important quality, shelf-life, myofibrillar functionality and food safety properties that improve the quality of meat and poultry products.

³ Sindelar JJ; Milkowski AL 2011. Sodium Nitrite in Processed Meat and Poultry Meats: A Review of Curing and Examining the Risk/Benefit of Its Use. American Meat Science Association White Paper Series. Number 13. <http://www.meatscience.org/SodiumNitriteReview.aspx>. Accessed November 14, 2011.

⁴ *Id.*

The role of sodium phosphates in meat products varies based on the level added and the form used. The most common sodium phosphates used are alkaline sodium phosphates. The primary role of alkaline sodium phosphates is to increase water-holding capacity by altering the ionic strength of the meat proteins to allow additional water molecules to bind to the protein.⁵ The increased water-holding capacity improves juiciness and also contributes to the texture of the meat product.^{6,7,8} Keeton and others observed that adding alkaline sodium phosphates to frankfurters increased Texture Profile Analysis attributes, particularly hardness, sensory panel attribute firmness, and amount of moisture in the raw and cooked products.⁹ Other phosphates such as sodium acid pyrophosphate have been utilized as acidulants for color stability, anti-microbial effects and texture improvement.^{10,11,12} Calhoun and others used sodium acid pyrophosphate with connective tissue in frankfurters to increase collagen solubility, which likely increased water binding capacity and texture within frankfurters.¹³

Combined with alkaline sodium phosphate, sodium chloride improves product texture.^{14,15,16} The functions of salt in a meat product are primarily improving food safety, extending shelf-life, for extraction and binding of myofibrillar proteins, and for flavor improvement.^{17,18,19,20} Altering ionic strength due to the addition of salt and

⁵ Pringle TD, Johnson LP, Bernkopf DK, Williams SE. 1996. Factors affecting purge losses in portion controlled steaks. *J Foodservice Systems* 9:93-105.

⁶ Knipe CL, Rust RE, Olson DG. 1990. Some physical parameters involved in the addition of inorganic phosphates to reduced-sodium meat emulsions. *J Food Sci* 55(1):23-25.

⁷ Boles JA, Swan JE. 1997. Effects of brine ingredients and temperature on cook yields and tenderness of pre-rigor processed roast beef. *Meat Sci* 45(1):87-97.

⁸ Detienne NA, Wicker L. 1999. Sodium chloride and tripolyphosphate effects on physical and quality characteristics of injected pork loins. *J Food Sci* 64(6):1042-1047.

⁹ Keeton JT, Foegeding EA, Patana-Anake C. 1984. A comparison of nonmeat proteins, sodium tripolyphosphate and processing temperature effects on physical and sensory properties of frankfurters. *J Food Sci* 49(6):1462-1465.

¹⁰ Hargett SM, Blumer TN, Hamann DD, Keeton JT, Monroe RJ. 1980. Effect of sodium acid pyrophosphate on sensory, chemical and physical properties of frankfurters. *J Food Sci* 45(4):905-911.

¹¹ Madril MT, Sofos JN. 1986. Interaction of reduced NaCl, sodium acid pyrophosphate and pH on the antimicrobial activity of comminuted meat products. *J Food Sci* 51(5):1147-1151.

¹² Calhoun CM, Eilert SJ, Mandigo RW. 1996. Connective tissue/acidic phosphate preblend effects on reduced fat frankfurters. *J Food Sci* 61(2):459-464.

¹³ See Calhoun *et al.* (footnote 12).

¹⁴ Stites CR, McKeith FK, Bechtel PJ, Carr TR. 1989. Palatability and storage characteristics of precooked beef roasts. *J Food Sci* 54(1):3-6.

¹⁵ See Boles and Swan (footnote 7).

¹⁶ Wynveen EJ, Bowker BG, Grant AL, Lamkey JW, Fennewald KJ, Henson L, Gerrard DE. 2001. Pork quality is affected by early postmortem phosphate and bicarbonate injection. *J Food Sci* 66(6):886-891.

¹⁷ MacFarlane JJ, Schmidt GR, Turner RH. 1977. Binding of meat pieces: a comparison of myosin, actomyosin and sarcoplasmic proteins as binding agents. *J Food Sci* 42(6):1603-1605.

¹⁸ Whiting RC. 1984. Stability and gel strength of frankfurter batters made with reduced NaCl. *J Food Sci* 49(5):1350-1354, 1362.

¹⁹ Medonca AF, Molins RA, Kraft AA, Walker HW. 1989. Effects of potassium sorbate, sodium acetate, phosphates and sodium chloride alone or in combination on shelf life of vacuum-packaged pork chops. *J Food Sci* 54(2):302-306.

²⁰ Waters, E. 2001. Ensuring fresh taste in cooked beef. *Meat Marketing and Technology* 11:62.

alkaline sodium phosphate increases binding of myofibrillar proteins and increases water-holding capacity to give meat products a more firm and uniform texture.²¹ The synergistic effect of salt and alkaline sodium phosphate has been shown to improve water-holding capacity, increase tenderness, increase pH, and increase cooking yield when compared to either ingredient individually.^{22,23,24,25,26,27} DeFreitas and others reported a lower protein transition temperature when two percent sodium chloride was added to pork muscle.²⁸ The addition of sodium chloride and alkaline sodium phosphate can alter not only protein denaturation, but also meat color by altering the ionic strength and pH of the muscle. The increase in water-holding capacity from salt and alkaline sodium phosphate causes a darkening of the muscle as the light reflection is reduced and more water is bound to the protein.²⁹

For the foregoing reasons, with respect to the decision-making process regarding sodium reduction recommendations, AMI respectfully requests that FSIS and FDA consider the possible unforeseen quality and functionality consequences of such recommendations.

Sodium Reduction Reformulation is Occurring in the Meat and Poultry Industry

The health of consumers is the driving force in producing meat and poultry products, which not only includes offering nutrient dense protein food products, but also in respect to improving and maintaining the safety of the food the meat and poultry industry produces. Still, in response to public requests the meat and poultry industry is actively involved in voluntary efforts to reduce sodium in products with more than 50 percent of the processed meat and poultry market undergoing recent sodium reduction reformulation. These products are consumed everyday by consumers.

²¹ Wu FY, Smith SB. 1987. Ionic strength and myofibrillar protein solubilization. *J Anim Sci* 65(2):597-608.

²² Ensor SA, Sofos JN, Schmidt GR. 1991. Differential scanning calorimetric studies of meat protein-alginate mixtures. *J Food Sci* 56(1):175-179.

²³ Shand PJ, Sofos JN, Schmidt GR. 1993. Properties of algin/calcium and salt/phosphate structured beef rolls with added gums. *J Food Sci* 58(6):1224-1230.

²⁴ See Detienne and Wicker (footnote 8).

²⁵ Robbins K, Jensen J, Ryan KJ, Homco-Ryan C, McKeith FK, Brewer MS. 2002. Enhancement effects on sensory and retail display characteristics of beef rounds. *J Muscle Foods* 13(4):279-288.

²⁶ Alvarado CZ, Sams AR. 2003. Injection marination strategies for remediation of pale, exudative broiler breast meat. *Poultry Sci* 82(8):1332-1336.

²⁷ Sen AR, Naveena BM, Muthukumar M, Babji Y, Murthy TRK. 2005. Effect of chilling, polyphosphate and bicarbonate on quality characteristics of broiler breast meat. *British Poultry Sci* 46(4):451-456.

²⁸ DeFreitas Z, Sebranek JG, Olson DG, Carr JM. 1997. Carrageenan effects on thermal stability of meat proteins. *J Food Sci* 62(3):544-547.

²⁹ Fernandez-Lopez J, Sayas-Barbera E, Perez-Alvarez JA, Aranda-Catala V. 2004. Effect of sodium chloride, sodium tripolyphosphate and pH on color properties of pork meat. *Color Research and Application* 29(1):67-74.

A survey of AMI members found that most companies have a high awareness of salt reduction initiatives and are responding by reformulating many processed products such as ham, bacon, hot dogs, and deli meats. AMI members indicate that they favor the gradual, step-wise sodium reduction strategies recommended by the Institute of Medicine (IOM)³⁰ because such an approach gives consumers time to adjust to sodium reductions and resulting changes in taste. Consumer acuity to salt is very sensitive and any reformulation must occur over extended periods of time to 1) ensure consumer acceptance, but more importantly, 2) ensure reformulation does not endanger the food safety profile of the meat and poultry products.

Many members indicated that they do not actively promote sodium reduction efforts to consumers out of concern that historical experience with reduced sodium products may prompt consumers to avoid products marketed in this manner. During the 1980s there was a period of public focus on sodium reduction in processed food that resulted in the development of many lower and low sodium products. The processed meat and poultry products introduced during this period had between a 15-25% sodium reduction, which was largely achieved via substitution of potassium salts for their sodium counterparts. During a five year period following their introduction, most of these products were withdrawn by manufacturers because of poor consumer acceptance. Only a few are available today and they are largely considered niche items.

Some companies are handling sodium reduction reformulation more quietly, fearing that such labeling is the marketing equivalent of a “skull and crossbones” label on a package. It is also important to note that all meat and poultry products bear a Nutrition Facts panel, which clearly states the sodium content of the product. Those products that qualify can also bear health claims for “no”, “low” and “reduced” sodium.

³⁰ IOM Report "*Strategies to Reduce Sodium Intake in the United States*" accessed April 25, 2010: <http://bit.ly/9urpv6>. On April 20, 2010, the IOM publicly announced their final report on Strategies to Reduce Sodium Intake. The IOM Committee recommended: FDA set mandatory nutritional standards for the sodium content in foods – not banning but reducing; FDA modify the GRAS status of salt and sodium-containing compounds added to processed foods to a level that is considered safe; the Secretary of HHS, in cooperation with governmental and non-governmental groups, design and implement a nationwide sodium reduction campaign as well as set a timeline for achieving sodium intake levels set by the *Guidelines*. These recommendations also encouraged industry organizations, health professionals and public-private partnerships to support implementation of sodium standards for foods and support consumers in reducing sodium intake. Additional monitoring of sodium intake and progress toward changing salt taste preference are also needed to track, evaluate and improve reduction efforts. The recommendations focused on a stepwise approach to ensure maximum health benefits and minimum consumer rejection. The IOM report also identified three main research needs: understanding how salty taste preferences develop throughout the lifespan; developing innovative methods to reduce sodium in foods while maintaining palatability, physical properties and safety; and enhancing current understanding of factors that impact consumer awareness and behavior relative to sodium reduction.

Products labeled “reduced” sodium or similarly are a small portion of current product categories (less than 10 percent of the category) as consumers have historically demonstrated poor purchasing behaviors. The strongest purchasers of these sodium reduced products are older Americans or consumers who are seeking products in response to health concerns.

The variety of options already available in the marketplace allows consumers to choose foods that are appropriate for their individual dietary needs. A mandate would stifle consumer choice and industry innovation.

FSIS and FDA Should Consider Institute of Medicine Report on Strategies to Reduce Hypertension in Americans

The FSIS and FDA *Federal Register* notice specifically cites the need for strategies to reduce sodium intake in Americans and cites the IOM report “*Strategies to Reduce Sodium Intake in the United States*” as one mechanism.³¹ Significantly, however, a February 2010 IOM report “*A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension*”³² appears to be ignored by FSIS and FDA.

The 2010 report outlines the economic burden that treating hypertension has on Americans and the U.S. healthcare system and how hypertension is simple to diagnose and inexpensive to treat. The IOM report states that other than modifying diet and exercise lifestyle behaviors, to achieve a successful reduction in hypertension rates in Americans, physicians should provide more consistent treatment as outlined in guidelines by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of Blood Pressure. The report found that more than 50 percent of physicians do not treat hypertension. The report suggests it is critical to encourage physicians to adhere to these guidelines to properly screen for and treat hypertension, especially in the elderly because a higher incidence of hypertension is an inevitable result of aging.

This IOM report does not ignore the role that sodium reduction can have in lowering hypertension rates, but it also focuses on the role of physicians treating hypertension, the effect of exercise, and other dietary modifications. AMI recommends that the IOM report “*A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension*” be considered by FSIS and FDA when developing any voluntary sodium reduction initiatives. As mentioned previously, to improve hypertension rates in Americans a physician education program highlighting the benefits of treatment of hypertension including proper screening and medical treatment for hypertension to include, but not limited to, medication, proper weight control, diet, and exercise, and other strategies targeted to at-risk populations.

³¹ IOM Report “*Strategies to Reduce Sodium Intake in the United States*”. Accessed April 30, 2010: <http://www.iom.edu/Reports/2010/Strategies-to-Reduce-Sodium-Intake-in-the-United-States.aspx>.

³² IOM Report “*A Population-Based Policy and Systems Change Approach to Prevent and Control Hypertension*”. Accessed February 25, 2010: <http://www.iom.edu/~media/Files/Report%20Files/2010/A-Population-Based-Policy-and-Systems-Change-Approach-to-Prevent-and-Control-Hypertension/Reduce%20and%20Control%20Hypertension%202010%20%20Report%20Brief.pdf>.

**USDA, FSIS and FDA Should Make Their Primary Focus Healthy Eating
and Lifestyle Approaches that Include Sodium Reduction in the Food Supply as
Only One Factor**

AMI supports the premise that eating a balanced healthful diet from all food groups and engaging in moderate exercise are the keys to a healthy lifestyle for Americans – including those health concerns commonly associated with sodium intake.

Summary

The meat and poultry industry is constantly evaluating new technologies as the industry investigates effective solutions for greater reductions over the long term. However, sodium reduction is complex. Similar to other food industry sectors, the meat industry must balance consumer taste preferences, food safety and functionality. This balance will not occur if it compromises product safety and just like our consumers will not compromise their preferences on taste and value.

The development of any voluntary sodium reduction initiatives should result in achievable, practical, and meaningful nutrition recommendations for the food industry that will result in the quantifiable improvement of American's health without unintended consequences.

AMI believes that consumers would be well-served by building on the USDA MyPlate education campaign reinforcing the importance of exercise, educating them in concrete and memorable ways about what types of foods should be consumed for optimal health and what a proper portion size looks like. This education program would support and strengthen the overarching message that a balanced diet needs to be eaten to maintain a healthy lifestyle. AMI would be pleased to work with USDA and FDA regarding each of these concerns

Thank you for your consideration of our comments. If there are any questions please do not hesitate to contact me at bbooren@meatami.com or 202-587-4249.

Sincerely,

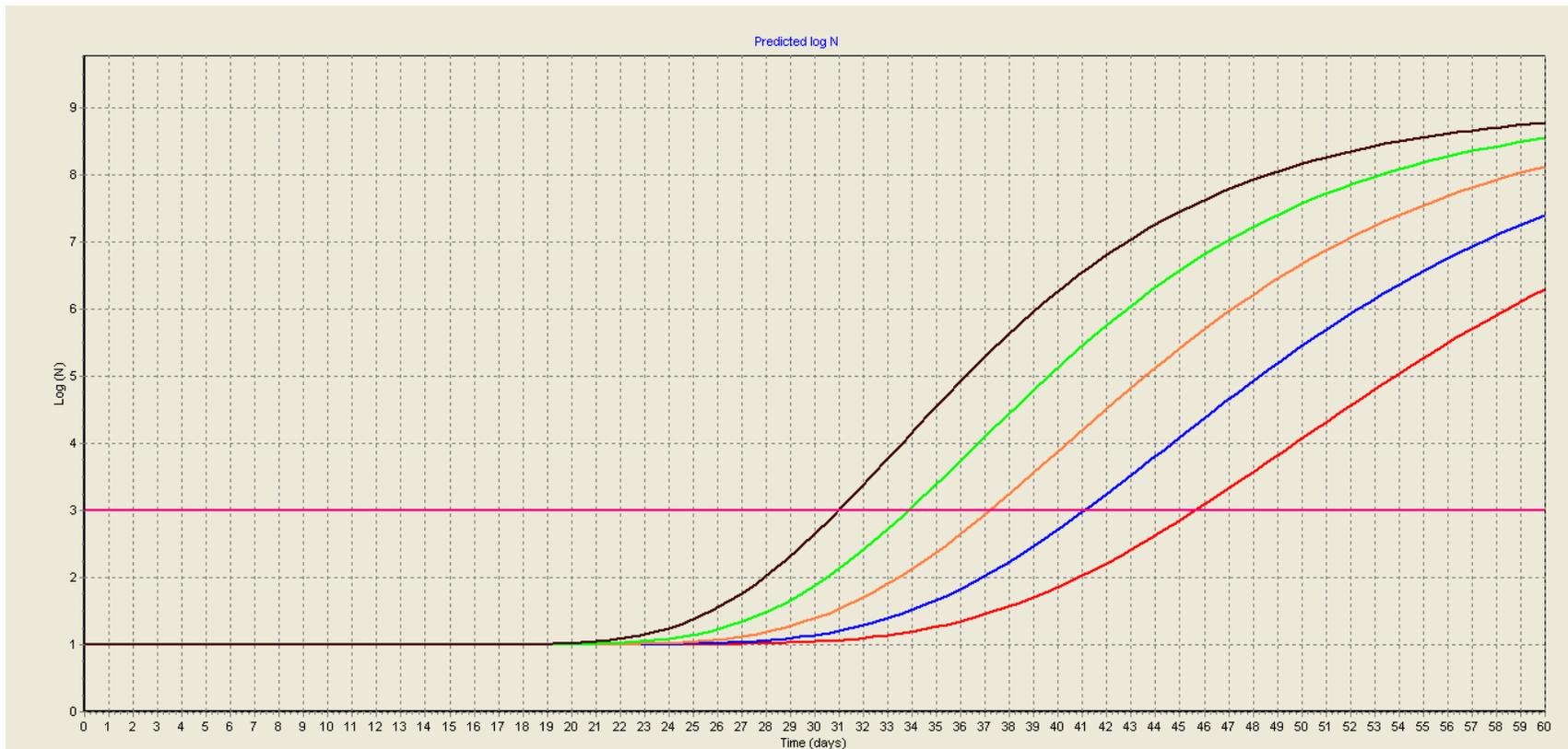


Betsy Booren, Ph.D.
Director, Scientific Affairs

cc: J. Patrick Boyle
Jim Hodges

Appendix A

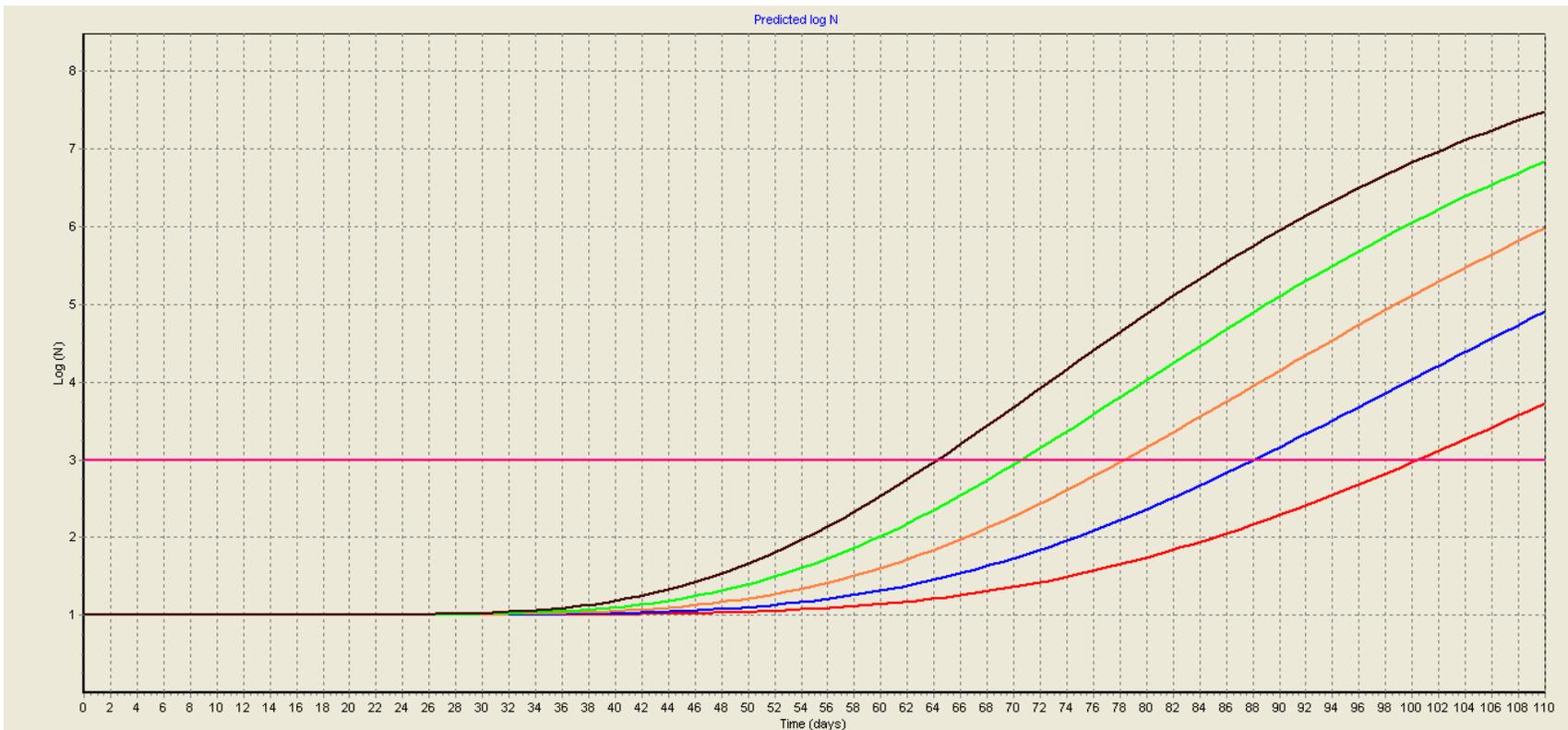
Listeria Growth Over Time with Varying Levels of Salt - Uncured Turkey Breast



Color	Salt %	Water Activity (a_w)	2 log <i>Listeria</i> Outgrowth (days)
	2.50%	0.9629	45 days
	2.00%	0.9671	41 days
	1.50%	0.9714	37 days
	1.00%	0.9757	34 days
	0.50%	0.9800	31 days

Product Parameters			
Temp: 41°F	pH: 6.30	Moisture: 75.00%	Opti.Form PD4: 3.50%

Listeria Growth Over Time with Varying Levels of Salt - Hot Dog



Color	Salt %	Water Activity (a_w)	2 log <i>Listeria</i> Outgrowth (days)
	2.50%	0.9536	100 days
	2.00%	0.9594	88 days
	1.50%	0.9653	78 days
	1.00%	0.9711	70 days
	0.50%	0.9769	64 days

Product Parameters			
Temp: 41°F	pH: 6.20	Moisture: 55.00%	Opti.Form PD4: 3.00%