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March 5, 2003

03-005N
03-005N-6
American Meat Institute
National Chicken Council
National Food Processors Association
National Turkey Federation

Docket No. 03-005N
Department of Agriculture
Food Safety and Inspection Service
Room 102
Cotton Annex
300 12th Street SW
Washington, DC 20250-3700

Re: Docket No. 03-005N: Draft FSIS Risk Assessment for Listeria in Ready-to-eat Meat and Poultry Products

To Whom It May Concern:

The American Meat Institute (AMI), the National Chicken Council (NCC), The National Food Processors Association (NFPA), and the National Turkey Federation (NTF) are submitting these comments on behalf of the meat and poultry products industries. The Food Safety and Inspection Service (FSIS; the Agency) draft risk assessment on *Listeria* in ready-to-eat (RTE) foods (the draft risk assessment) directly affects our members.

AMI, NCC, NFPA and NTF (the associations) support the use of risk assessments to help provide risk estimates, and to better assess control options. A well-done risk assessment can provide useful scientific advice to risk managers. A desired level of consumer protection can be sought using risk management options. This is a very interactive process where all stakeholders should be involved to gain consensus and create benefits for everyone involved to optimize success. A key to the success of improvements in public health is a thorough and adequate risk assessment. When one considers the multitude of RTE meat and poultry products, the diverse processing operations used to produce these products, and the different interventions used along the production and distribution pathways, the complexity of the risk assessment becomes apparent. The FSIS risk assessors have done a phenomenal job in a short time frame of putting together a model to assess a very complex scenario – the transfer of *L. monocytogenes* in the

environment to deli meats. This should be considered the beginning of an interactive process of peer review, submission of additional data, revision and re-review.

The risk assessment has two components, an in-plant model that links to the updated FDA/FSIS risk-ranking model, which will not be released until this summer. Information on the in-plant model was released on February 14 and more specific risk assessment results were presented at a public meeting February 26 and made available in hard copy. Even with this presentation, there is a lack of transparency in how this risk assessment arrives at its findings, in part because the revised FDA/FSIS risk-ranking model is not yet available and because there has been no external use of the models. There has been very limited time for any review of these complex models and the data and results on which FSIS is basing its findings and, presumably, rulemaking activity. Our members have looked at the in-plant model and have identified a number of problem areas with respect to its assumptions and its application.

We recognize that in all risk assessments there must be assumptions made, especially when data are limited, and there are always alternative assumptions that can be applied. Caution should be taken in extending extrapolations from single events or single scientific studies to such a complex universe of RTE meat and poultry products. The model focuses on deli meat, but the risk management questions, the findings and, presumably, the application of these are for all RTE meat and poultry products. If data are appropriate for a single class of products, e.g., deli meats, then the focus of the risk assessment should be on that class, understanding that future research and risk assessments can be directed toward another class of products, as well as closing the data gaps for the draft deli meat risk assessment. Throughout this document there is reference to RTE meat and poultry products. We urge FSIS to revise the language to clarify when a statement appropriately applies to all RTE products and when it should be limited to deli meats. In particular, the title should refer to deli meats and not RTE meat and poultry products. When applying the findings, the Agency should carefully consider whether the risk assessment supports application to the product in question or whether they should be limited to certain classes of products such as those that support growth of *L. monocytogenes*.

Ultimately there should be more focus on how the risk assessment applies to the risk from products that do not support growth of *L. monocytogenes* as a result of reduced pH, water activity, or frozen storage, in addition to inhibitors.

The associations believe that environmental monitoring to find *Listeria* and, when a positive result is found, taking immediate diagnostic and corrective actions followed by verifying efficacy is the best means of controlling *Listeria*. The success of the corrective action will determine many events, such as the duration of the problem, the concentration of any contamination, the type of sampling and testing protocols needed, and the actions needed to ensure that the source of contamination does not reoccur. The key is having programs that aggressively look for *Listeria* in the environment and preventing the establishment of *L. monocytogenes* in niches by taking action on these positives.

Whether or not the contamination is from a niche or other similar harborage point or from a transient source, the contamination may or may not have the potential to directly impact food contact surfaces or product. These considerations should be taken into account during the development of any risk assessment involving RTE meat and poultry products.

PROBLEMATIC ISSUES IN THE DRAFT FSIS RISK ASSESSMENT

The associations find the following general issues problematic in the draft risk assessment, and strongly urge FSIS to revisit these issues before using the draft risk assessment for any policy or regulatory action. These issues are described in some detail in the following discussions.

1. The model assumes that the *L. monocytogenes* contamination comes from a reservoir (a niche, or harborage site) in the plant, without consideration for contamination from sporadic positives or contamination arising at retail.
2. The draft risk assessment fails to consider the operational parameters associated with processing deli meats and other RTE meat and poultry products. These factors are significant to the discussions of product contact surfaces and other such issues raised as major considerations in the draft risk assessment. Failure to examine the operational

factors in detail greatly reduces the value of the draft risk assessment in delivering an appropriate and useful risk estimate.

3. The draft risk assessment makes unrealistic estimates of the efficacy of sanitation and corrective actions that are critical to the success of on-going control of *Listeria* in processing environments. The efficacy of post-packaging treatments is also unrealistically low.
4. All current, relevant scientific literature and industry data have not been integrated into the draft risk assessment. There is an over-reliance on single sets of data to develop the draft risk assessment when, in some cases, additional data were available. The draft risk assessment does not provide all references cited in the document.
5. In many cases the draft risk assessment fails to provide adequate support for the assumptions, variability and uncertainty for the model parameters. In some cases the draft risk assessment appears to use unrelated and inappropriate data as bases for its mathematical calculations, greatly decreasing the potential validity of the draft risk assessment, particularly in relation to the transfer coefficient. Furthermore, data and opinions unrelated to the scope of the draft risk assessment are included.
6. The draft risk assessment should describe in more detail the limitations of sampling and testing programs to detect low level prevalence of *Listeria*, whether on food contact surfaces or in RTE products. Oversimplification leads to unscientific conclusions relative to sampling and testing as a means to control *Listeria*, particularly in operations where *Listeria* control programs are very effective in reducing the likelihood of *Listeria* being present, or persisting, in the processing environment.
7. The draft risk assessment should provide more consideration to the numerous intervention technologies in use to help control *Listeria*, particularly where *L. monocytogenes* is not a hazard reasonably likely to occur because of control procedures addressed in the Sanitation SOPs and other programs, as acknowledged in the draft risk assessment by FSIS.
8. The draft risk assessment was not released for "use and experimentation" by interested stakeholders, providing no opportunity for further, "hands-on" analysis of the draft risk assessment before the comment period was over. The FSIS draft risk assessment needs to be reviewed by an independent, expert third-party.

The model assumes that the *L. monocytogenes* contamination comes from a reservoir (a niche, or harborage site) in the plant, without consideration for contamination from sporadic positives or contamination arising at retail.

While the scenario of an in-plant reservoir presents the highest risk of listeriosis if the strain is virulent, it must be recognized that most findings of *Listeria* in a plant represent transient, sporadic positives. Rarely do these positives for *Listeria* spp. or *Listeria*-like organisms (even on food contact surfaces) lead to detectable *L. monocytogenes* in product. In addition, the risk assessment assumes that all contamination at retail arose from contamination at the manufacturing plant. Data submitted to this docket (dated February 24, 2003) in a pre-publication galley (Gombas, et al., 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. *J. Food Protection*, in press) demonstrates this is not the case.

The draft risk assessment fails to consider the operational parameters associated with processing deli meats and other RTE meat and poultry products. These factors are significant to the discussions of product contact surfaces and other such issues raised as major considerations in the draft risk assessment. Failure to examine the operational factors in detail greatly reduces the value of the draft risk assessment in delivering an appropriate and useful risk estimate.

The issues surrounding the impact of operational parameters on the draft risk assessment are discussed elsewhere in this document; however these are significant enough to state them collectively here. Operational parameters will affect the following elements of the draft risk assessment and should be developed more completely, in partnership with industry, before the risk assessment is used for policy decisions or regulatory action.

- Duration of contamination persistence,
- Time between contamination events,
- Risk reduction through interventions,

- Extent of transfer between food contact surfaces and products,
- The potential for harborage in an establishment,
- The area of product contact surface,
- The potential for growth of contamination on products,
- The amount of product produced in a lot,
- Effectiveness of corrective actions,
- Effectiveness of sanitation,
- The likelihood of contamination in a plant, regardless of size, and
- The sampling and testing program implemented in the establishment.

Furthermore, the model assumes that, for most of these operational parameters, they apply to all plants equally regardless of plant size. We believe the model can be improved by using different approaches and assumptions for different size plants (large, small and very small). The assumptions need to reflect the different practices that take place in plants, which are often more stringent in large establishments than in less sophisticated plants, including sanitation practices and their efficiency, testing protocols for the environment and product, food contact surface area tested, frequency of positives, and interventions, including the use of inhibitors and post-packaging pasteurization. With the new Directive in place and the increased sharing of data, much of this information will be available for use in a revised risk assessment.

The draft risk assessment makes unrealistic estimates of the efficacy of sanitation and corrective actions that are critical to the success of on-going control of *Listeria* in processing environments. The efficacy of post-packaging treatments is also unrealistically low.

The draft risk assessment states on page 21 that there is "limited data on the effectiveness of sanitation in reducing the level of *Listeria* species on food contact surfaces." The proposed assumptions of 75% for daily sanitation, obtained by expert elicitation within FSIS, would seem to be out of step with FSIS inspection data on the number of production lines that are acceptable for daily operations every production day. The basis for the 75% efficiency does not appear to

be as well grounded in available data as possible. If the end of the day sanitation were only 75% effective, there would be major spoilage problems in meat and poultry products and much shorter shelf lives. It would not be unrealistic to assume, based on industry experience, 99 to 99.9% efficiency for base sanitation. Likewise, setting 95% as the effectiveness of the "enhanced cleaning" needs supporting data or better expert elicitation. It would be more likely that the efficacy would be closer to 100% since establishments verify the efficacy of their enhanced cleaning and sanitation before production resumes, or before product is released. FSIS could improve their understanding of the efficacy of sanitation by participating with industry in the evaluation of the sanitation and corrective actions.

The 90 to 95% efficiency for interventions such as high pressure processing and post-packaging heat treatments are also low. These processes are designed to kill levels of *L. monocytogenes* that would arise from environmental contamination. If the organism is not there, there is no risk. The model should reflect close to 100% effectiveness for this parameter.

The model should be revised and re-run using these more realistic parameter inputs.

All current, relevant scientific literature and industry data have not been integrated into the draft risk assessment. There is an over-reliance on single sets of data to develop the draft risk assessment when, in some cases, additional data were available. The draft risk assessment does not provide all references cited in the document.

On pages 12 and 13, FSIS appears to use a single in-depth verification review to predict the frequency of a contamination event. This is an unpublished report, and thus, likely has not been peer-reviewed, yet it appears to be accepted as the sole basis for estimating the time between contamination events. Moreover, since this information is not publicly available, it is not clear how the data were obtained or how representative these data are for other establishments, even those with a harborage event. In fact, the risk assessment notes that it is not known how representative the data are compared to other plants. The data are fit to a lognormal probability

plot, as are the data for duration. We would like to see all distributions as cumulative frequency distributions such as in Figure 10, as these are more readily interpretable than Figures 2 and 3.

It is important that FSIS not use these data in isolation to predict the frequency of a contamination event. The data has not been reviewed, and represents a single event where it was possible that *Listeria* control was not adequately practiced. Data are needed for the frequency of contamination events from establishments where an effective *Listeria* control program is in place; these data should be more readily available under Directive 10,240.3, where establishments share their *Listeria* control programs with FSIS.

A statement on page 14 indicates that the data from this IDV do not tend to exhibit the duration seen in other data, but it is not clear what these other data are (the Tompkin data?). If the data from the IDV are not consistent with other data, then the assumption that they accurately represent frequency may also be in question.

The use of single data sets to generate conclusions occurs in the prediction of the duration of an event as well (page 15). The data in the model for duration of an event are based on published data by Tompkin. The data in the publication indicate that 4.9% of the data sets represent three consecutive positives. Industry has presented additional data showing this percentage can be much lower (a fraction of a percent), but the data were not included. Moreover, without subtyping data (e.g., PFGE, ribotyping) the questions as to whether or not the same *Listeria* strain was isolated in all situations and how representative the data used are of contamination persistence remain to be addressed before these data should be considered as sufficient to establish a timeframe for duration. It is very likely that different operational and sanitation practices, product type, corrective actions and other factors greatly influence duration.

Footnote #9 on page 4 provides what seems to be an FSIS opinion, i.e., "may indicate that the establishment has a serious sanitation problem," without a scientific, published report used as a reference. This type of speculation seems inappropriate in a risk assessment document, particularly if the data supporting such a claim are not provided for review. The NFPA citation in footnote #11 on page 5 refers to comments submitted to the Agency; it is not included in the

list of references nor is a complete citation given in the footnote. Similarly, footnotes 7 and 12 refer to submitted comments. Comment dates and docket number should be provided.

In the first paragraph in the section entitled "Model Overview" on page 6, there is a statement that "...the fraction of *Listeria* that transfer from the food contact surface to the lot varied from lot to lot, but fell within a limited range and matched the probability distribution of the available data." The data referenced is not specified, nor is there a discussion of how representative these data are for all RTE meat and poultry products, establishments, and operating systems.

The model assumes there are two shifts per day for 30 days per month. FSIS conducted a survey of RTE plants that should provide more accurate data on shifts per day and production days per month by plant size. It is not clear why these data were not used, since production volumes by plant size were apparently used in the model.

It is important that a draft risk assessment is transparent; and part of this transparency means having all data used properly referenced. Where the risk assessors have relied on expert elicitation, this should be explicitly stated. The Midelet and Carpentier (2002) reference is not provided in the reference list at the end of the document. Relevant data from Dr. John Luchansky, ARS, while perhaps used in part, is not referenced; although it is our understanding that the peer-reviewed article is now in-press. Furthermore, data on interventions, such as the use of lactate and diacetate to prevent growth during distribution, which has been published (Seman et al., 2002. Modeling the growth of *Listeria monocytogenes* in cured ready-to-eat processed meat products by manipulation of sodium chloride, sodium diacetate, potassium lactate and product moisture content. *J. Food Protection* 65: 651-658), is not included. Attached to this document is an example of the use of a commercial formula of lactate and diacetate to control the growth of *Listeria* at 40 °F, with a second attachment demonstrating the benefits to public health of reducing the concentration of *L. monocytogenes* in product consumed by the consumer.

The footnote (#8) on page 4 of the draft risk assessment that defines indicator organisms uses a definition that seems out-of-step with current accepted definitions for indicator organisms; the

National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 2002)[1] defines indicator organisms as those organisms that define a state or condition, in contrast to index organisms that correlate with the frequency or concentration of another organism of concern.

In many cases the draft risk assessment fails to provide adequate support for the assumptions, variability and uncertainty for the model parameters. In some cases the draft risk assessment appears to use unrelated and inappropriate data as bases for its mathematical calculations, greatly decreasing the potential validity of the draft risk assessment, particularly in relation to the transfer coefficient. Furthermore, data and opinions unrelated to the scope of the draft risk assessment are included.

Although it is recognized that assumptions may be necessary in risk assessments, it is a standard practice that the effects of the assumptions on the final risk estimate need to be stated clearly. The draft risk assessment does not clearly define the effects of the many assumptions made throughout the draft. We recommend that whenever assumptions are being made full disclosure and analysis of the effects of such assumptions be presented in the draft risk assessment. The draft risk assessment could do more to identify, describe and, where possible, quantify sources of variability and uncertainty that will affect the validity of the outputs of the draft risk assessment.

In a technical draft risk assessment such as the one under discussion, it would be advisable to prepare a table of all of the assumptions being made in the risk assessment. Table 1 does do this to a limited extent, but does not provide adequate description of the effect of these assumptions on any final risk estimate. Some of the assumptions for which the associations believe it is necessary to conduct a more in-depth analysis include the following:

- The assumptions that interventions do not change the time between contamination events, the duration of an event or the amount of contamination transferred from a food contact surface do not appear to be valid, and would appear to have a

[1] NACMCF. 2002. Response to Questions posed by FSIS regarding performance standards for ground beef products.

significant effect on any risk estimate. Interventions (as described by FSIS in the draft risk assessment) may include routine operations and corrective actions such as routine and focused sanitation, respectively, that would greatly impact time, duration and concentration. Focused sanitation and other interventions can eliminate the harborage, thereby ending the contamination event. Even in instances where the harborage is not eliminated, depending on the nature of the harborage the intervention could reduce the numbers of *L. monocytogenes* in the niche, delaying contamination of food contact surfaces, thereby increasing the time between events.

- The assumption that plant size affects food contact surface area, and thus contamination events, fails to consider that plant size is much less relevant than factors such as process line configuration, *Listeria* control program implementation, and packaging technology.
- There are no assumptions provided for transfer from food contact surfaces, even though product configuration (e.g., stacked, shingled) and surface physical characteristics could affect transfer. On page 7, it is stated that the model assumes *Listeria* species are evenly distributed across food contact surfaces, and that *L. monocytogenes* is evenly distributed within product, i.e., "the variability across a food contact surface or across a lot is not accounted for in this model." While such assumptions and dismissal of variability may simplify the model, these assumptions are clearly not valid, based on operational parameters, food product design and formulation, product packaging processes, and the process of contamination, e.g., from niches or other harborage sites or from transient contamination. The risk assessors stated that they have no data to model a different assumption, yet in other instances where data were lacking, they used expert elicitation. We urge the Agency to similarly model alternatives to uniform distribution on food contact surfaces and in product.
- The assumption that prevalence distribution is similar to concentration distribution needs additional validation. Industry experience has shown that contamination, when it occurs, may be sporadic, in clumps and not routinely occurring at some consistent frequency.

- The assumption that the growth multiplier should be fixed at one log for all lots is an oversimplification and will have an effect on the risk estimate. Cold chain management, distribution time, product formulation, microbiological species and other considerations need to be integrated into the assumption of growth, with full understanding of how each of these impacts any potential growth during transportation to retail.
- The model uses an average transfer coefficient based on data in the literature for three different product surfaces but does not include some critical data provided by industry. Transfer coefficient is discussed in more detail below.

One of the weaknesses of the draft risk assessment is the use of unrelated and inappropriate data for determination and estimation of the transfer coefficient. A review of the references cited in this section indicates that the transfer data from these citations are based on vehicles or vectors, and products unrelated to the risk assessment under development. In particular, the Midelet and Carpentier study apparently used raw beef, clearly different from RTE product. The standard deviation for the transfer coefficient was derived from a study using a Gram-negative organism and may not be applicable for *L. monocytogenes*. The study also modeled transfer in food service operations. There are no data to demonstrate that raw meat transfer is similar to RTE meat, that food service operations parallel production of RTE meat and poultry products, and that gloved hands are similar to food contact equipment surfaces. In the food-processing environment, there are many factors that would impact transfer including the type of point source contamination (e.g., niche in equipment or gloved hand), the type and physical nature of the RTE food product, and the type of product assembly, if any, necessary before packaging. An example of articles that may be of value for assessing transfer of contamination is that of Lunden, Autio and Hannu (Transfer of persistent *Listeria monocytogenes* contamination between food-processing plants associated with a dicing machine. *J. Food Protection* 65 (7): 1129-1133, 2002). Moreover, the model apparently ignores data provided to the Agency from a study on transfer sponsored by industry and conducted by the University of Georgia showing that there is no transfer to finished product at low levels found on product contact surfaces. The rationale for this was that the data were presence/absence data, rather than quantitative. However the data

provide very useful sequence of contamination information and demonstrates that where there is no continuing source of contamination the duration of the contamination event is limited.

Although the risk management questions do not relate to non-food contact surfaces, as stated on page 5, the footnote #13 on this page, discusses non-food contact surfaces such as air, floors, machine parts and walls. This section does not seem relevant to the draft risk assessment or the specific risk management questions. If it is to be included, the data from the in-depth verifications should be provided; and it should be clear as to whether these data have been published and are peer-reviewed.

The draft risk assessment should describe in more detail the limitations of sampling and testing programs to detect low level prevalence of *Listeria*, whether on food contact surfaces or in RTE products. Oversimplification leads to unscientific conclusions relative to sampling and testing as a means to control *Listeria*, particularly in operations where *Listeria* control programs are very effective in reducing the likelihood of *Listeria* being present, or persisting, in the processing environment.

In the discussion of the model parameters (pages 7 and 8), the conceptual model (pages 9 and 10, Figure 1), and the sources of data and assumptions (pages 12 and 13, Table 1), microbiological testing is presented as a tool to accept or reject product, and to establish the acceptability of food contact surfaces. In the outputs given on page 26, testing is given as an example of an intervention. It has become well established that microbiological testing is not an intervention, as is the use of chemical inhibitors, for example. In order to define sampling and testing programs, it is necessary to define the prevalence of the pathogen, the sensitivity and selectivity of the assay, and the number of samples being taken from a lot. With several underlying assumptions (e.g., homogeneous distribution of the pathogen), these inputs will provide a probability of excluding defective lots. These analyses should be incorporated into the draft risk assessment, clarifying the expected level of control with a sampling and testing protocol given in the draft risk assessment model.

Evidence should be given to support the assumption of 75% efficacy of finding one cell, given its presence in the sample. Furthermore, we recommend that a comparison be made between model results and sampling statistics published by ICMSF (*Microorganisms in Foods* 7, 2002). For example, published tables and statistical sampling curves show that with a lot containing 2% positives if three samples are taken there is a 94% chance on not detecting a positive and there is a 30% chance of missing a positive even when 60 samples are taken. It is not clear whether the model generates results consistent with these published statistics.

The draft risk assessment should provide more consideration to the numerous intervention technologies in use to help control *Listeria*, particularly where *Listeria monocytogenes* is not a hazard reasonably likely to occur because of control procedures addressed in the Sanitation SOPs and other programs, as acknowledged in the draft risk assessment by FSIS.

The draft risk assessment states "FSIS acknowledges that there may certain processing operations in which *L. monocytogenes* is not a hazard reasonably likely to occur." It continues to state that verification testing of food contact surfaces may be appropriate. Although there is FSIS recognition of operations where *L. monocytogenes* is not a hazard reasonably likely to occur, it is not clear how this consideration integrates into the model, since it impacts the total volume of RTE meat and poultry products that potentially could contain *L. monocytogenes*.

The draft risk assessment was not released for "use and experimentation" by interested stakeholders, providing no opportunity for further, "hands-on" analysis of the draft risk assessment before the comment period was over. The FSIS draft risk assessment needs to be reviewed by an independent, expert third-party.

It would be advantageous to share the draft risk assessment model with all stakeholders in order to obtain a more complete review of the draft risk assessment. Requests for the model to date

have been denied, although the in-plant model is apparently designed to be user friendly, allowing users to easily change data required to run the model (page 19).

CONCERNS REGARDING OUTPUTS AND FINDINGS

The model was developed to address specific risk management questions that were based in part on a rule proposed in February 2001. We are concerned that the findings from the risk assessment may be inaccurate and misleading given the concerns about assumptions in the risk assessment. Moreover, companies may be required to change practices that have been shown to be effective in addressing contamination from *L. monocytogenes* in their facilities because their practices were not considered in the model. The model does not consider the impact of environmental (non-food contact) testing on preventing contamination of food contact surfaces and product. The risk assessment could be interpreted as suggesting that testing one food contact surface or testing one product sample for each lot produced could be an effective approach for reducing *L. monocytogenes* concentrations at retail (Figure 15, page 32), when industry experience, and many published papers on microbiological sampling and testing, would not support this.

We would not disagree with the findings that post-packaging interventions or formulations with growth inhibitors can significantly reduce levels of *L. monocytogenes* at retail – the risk assessment, even with inaccurate assumptions simply reinforces industry's belief that where such interventions are available, practical, have been validated, and can be applied to a specific product, they should be used. The model predicts greater public health impact when post-packaging treatments and growth inhibiting formulations are used together. We believe this is a result of improper assumptions during the modeling (the 90 to 95% efficiency of each of these interventions) and recommend re-addressing this issue after revising the inputs as we have suggested in our comments. This is critical, since this combination was the only scenario tested where the estimated total number of deaths fell below 100 per year (page 33), and could result in the Agency implementing overly stringent requirements. In fact, the risk assessors did run one scenario in which they assumed post-packaging treatments were 99% effective in comparison to

95% effective, with a significant increase in lives saved, approaching that of the combination of post-packaging intervention and growth inhibitors.

The risk assessment conclusion that the likelihood of finding RTE product positive for *L. monocytogenes* greatly increases when food contact surfaces test positive for *Listeria* spp. is not consistent with industry experience. This conclusion may follow from the assumptions that there is a reservoir in the plant and that the contamination event is ongoing, along with the assumptions of 75% efficiency in finding a positive food contact surface and product sample (given uniform distribution); however, it is not clear that this would hold true when contamination is a transient event with low numbers of organisms, resulting in limited contamination unlikely to be detected.

The summary statement that the frequency of contamination of food contact surfaces with *Listeria* spp. encompasses a broad timeframe with a one-week duration is erroneous in most contamination events. It may be a reasonable assumption in a harborage situation; however, a number of companies have presented data to FSIS that indicate harborage events are rare occurrences when an establishment follows a validated *Listeria* control program. In fact, this statement does not belong in the summary, as it represents inputs to the risk assessment, not outputs.

It is interesting to note that the frequency of testing in the proposed rule would have resulted in only a small reduction of risk, according to this risk assessment. Clearly the recent criticism of the Agency for not implementing the rule, thereby preventing recent illnesses and deaths, is unfounded. This underscores the importance of conducting risk assessments to support policy decisions.

While industry supports the need to conduct environmental and food contact surface testing and take action when positives are found, we do not believe the summary statement that increased frequency of food contact surface testing and sanitation leads to a proportionally lower risk of listeriosis is completely accurate, given the issues we have with some of the assumptions made in the risk assessment.

The risk assessment conclusion about combinations of interventions being much more effective than single interventions may be partially correct; however, we have already noted concerns about this conclusion with respect to combining post-packaging treatments (e.g., heat, irradiation) with growth inhibiting formulations. We agree that combining environmental testing with other interventions such as post-packaging lethality treatments, inhibitors or freezing products, whose effectiveness is generally predicated on low levels of *L. monocytogenes*, can enhance our efforts to reduce the risk of illness or death from *L. monocytogenes*.

FINAL COMMENTS

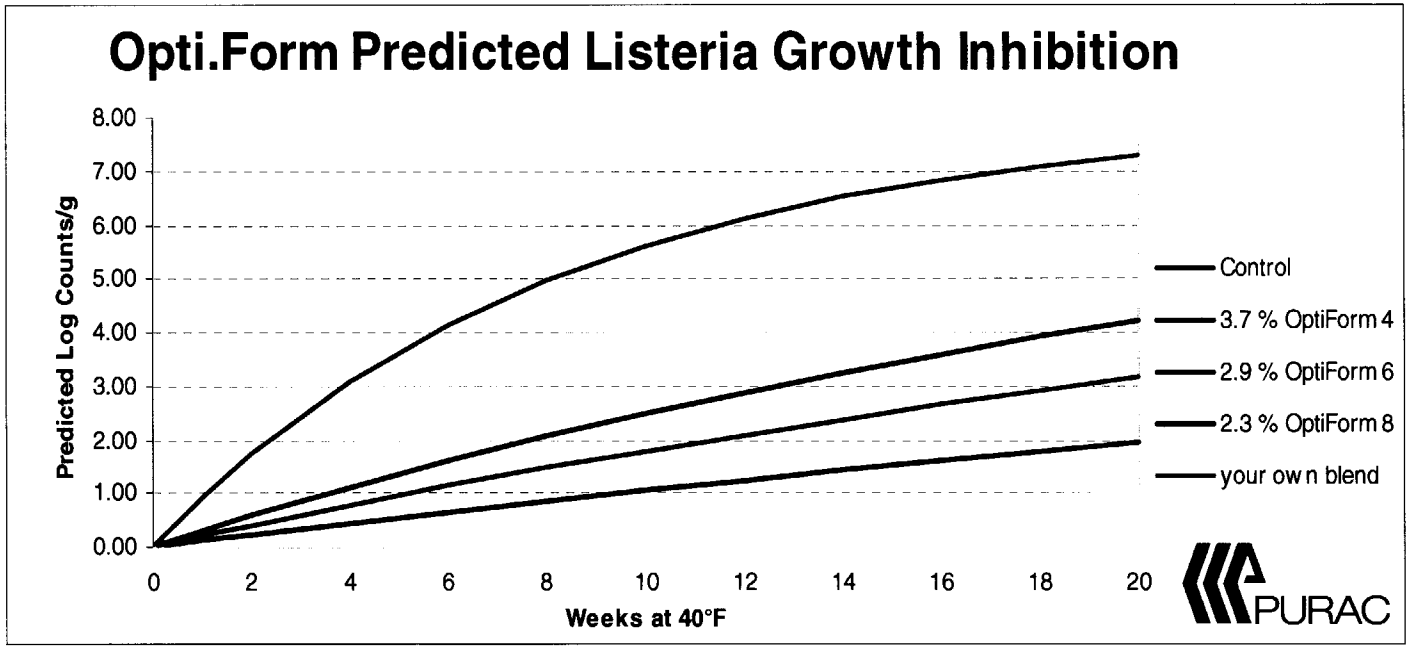
The associations believe that the draft FSIS risk assessment model is a beginning, not an end. The draft illustrates the many deficiencies in the data available for an accurate and useful risk assessment. The associations support the continued development of data to achieve useful and defensible risk estimates that would allow appropriate risk management options to be proposed. The associations believe that the most effective means to achieving the public health goals for RTE meat and poultry products is to involve all of the stakeholders in the discussion of risk assessments and risk management, and welcome the opportunity to participate even more actively in the effort. Thank you for the opportunity to comment on this important draft risk assessment.

Sincerely,

American Meat Institute
National Chicken Council
National Food Processors Association
National Turkey Federation

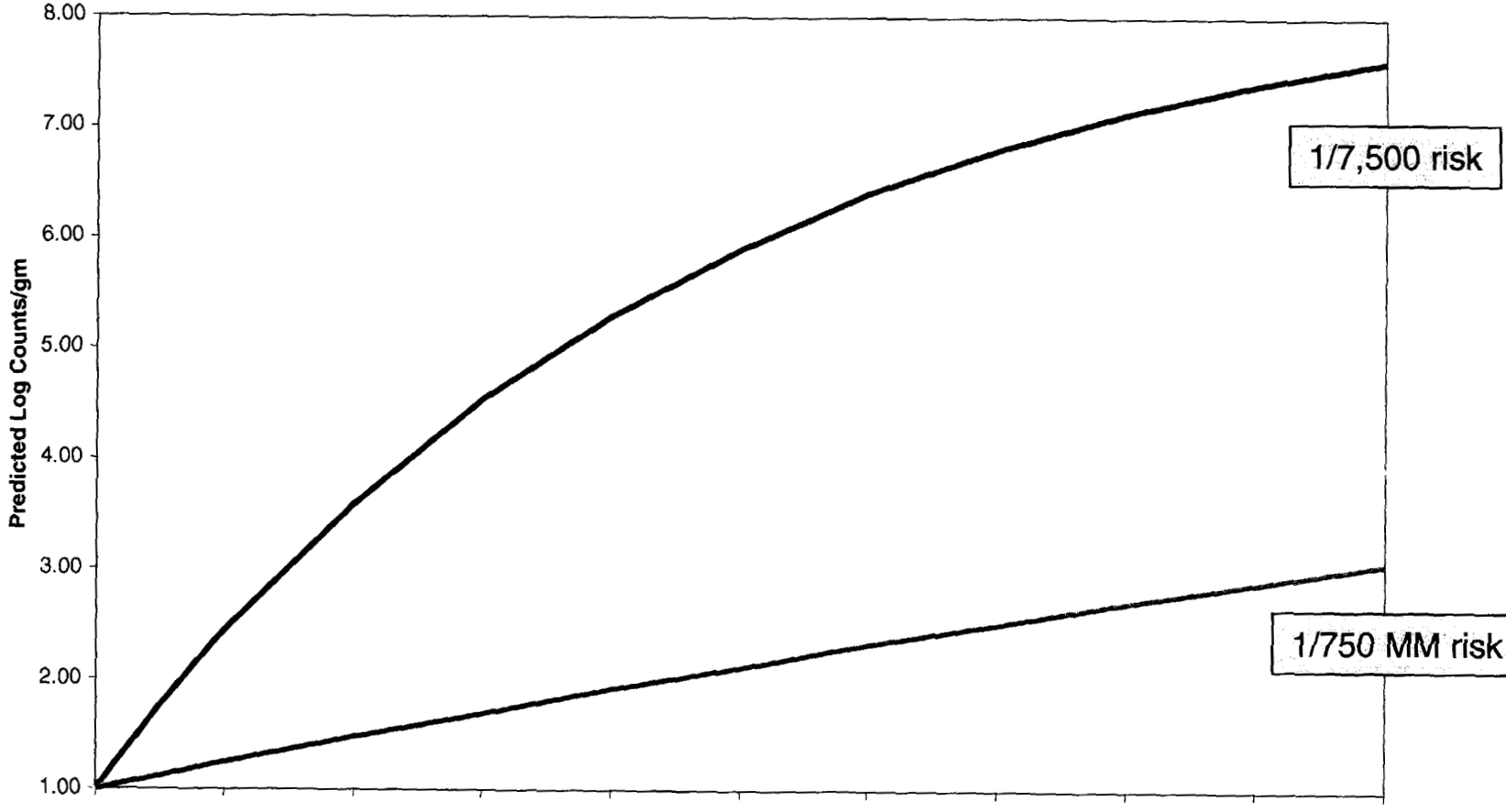
Commercial use as the PURAC America Opti.Form

Level of use		3.7	2.9	2.3	
	Control	*% OptiForm 4*	*6*	*% OptiForm 8*	*your own blend*
Product Ingredients	*% of Finished Product*	*% of Finished Product*	*% of Finished Product*	*% of Finished Product*	*% of Finished Product*
Salt (%) =	2.50	2.50	2.50	2.50	2.50
Sodium Diacetate (%) =	0.00	0.15	0.17	0.18	0.00
Potassium Lactate (%) =	0.00	2.07	1.57	1.20	0.00
Finished Product Moisture (%) =	75.00	75.00	75.00	75.00	75.00
Calculated 60% lactate solution used in your own blend:					



Oscar Mayer Foods is not in any way affiliated with the development, sale or efficacy of PURASAL Opti.Form or any other products by PURAC

Listeria Growth Inhibition
Estimated Benefit to Public Health*



*Based on Growth Model and **Median** mortality risk
for neonates published in FDA/USDA risk analysis Figure IV-5