Kraft Foods

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10

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United States Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

03-005N
03-005N-10
Jean E. Spence

Re: FSIS Draft Risk Assessment for Listeria in Ready-to-eat Meat and Poultry

Dear Sir or Madam:

Kraft Foods (Kraft) is the largest branded food and beverage company headquartered in the United States and the second largest in the world.[1/] Each year, Kraft is responsible for introducing into commerce about 18 billion individual packages of food. Our brands are found in more than 99% of all households in the U.S.[2/] Consumers have trusted our products for many decades. Indeed, the safety of our food products is the essential foundation upon which the success of our business is built. Consequently, food safety regulation is of paramount importance to Kraft.

Kraft strives to be an industry leader in the development and implementation of science-based programs and technologies designed to enhance food safety. In recent years, we have learned a great deal about food safety programs and techniques that work much more effectively than those previously in place, as well as those that did not prove to be as effective as intended. In these comments on the draft risk assessment for processed meat and poultry products, we are pleased to share what our company has learned. We approach this task realizing that all stakeholders must view food safety as a common, shared goal, if we are to be successful as a nation in preventing food borne illness.

1/ "Kraft Foods" and "Kraft" both refer to Kraft Foods North America, Inc., including its wholly owned subsidiary Kraft Foods International, Inc. The company's pro forma revenue, including Nabisco, for the year 2002 was roughly $30 billion.

2/ This level of market penetration is based on statistics gathered by A.C. Nielsen. Our well-known brands of products containing meat or poultry include Oscar Mayer, Lunchables, Louis Rich, Tombstone, Di Giorno, Jack's, California Pizza Kitchen, and a variety of products sold under the Kraft brand.

Intent of the Risk Assessment

Kraft commends FSIS for the agency's efforts to support food safety regulations with strong science-based risk assessment methodology. Kraft also commends FSIS for responding thoughtfully to public comments requesting stronger scientific evidence to support the requirements of the proposed rule: *Performance Standards for the Production of Processed Meat and Poultry Products* (66 FR 12589, February 27, 2001, comments due September, 2001). Given the relatively short timeframe the FSIS risk assessors had to address a complex issue, transfer of *Listeria monocytogenes* from environmental sources to deli meats, the risk assessment published on February 14, 2003 should be viewed as an additional step rather than the final step in developing the risk assessment upon which the final RTE Rule ultimately will be based.

FSIS and the food industry share the responsibility to develop science-based strategies that reduce the potential exposure of susceptible consumers to infective levels of *L. monocytogenes* in RTE meat and poultry products. Kraft is convinced that, as a matter of good manufacturing practice, all producers of ready-to-eat (RTE) meat and poultry products should institute *Listeria* control programs that include an environmental testing component. These programs should be designed to identify and sanitize *Listeria* harborage sites in the processing environment and to provide data upon which manufacturers can base corrective actions. In addition to programs designed to maintain a sanitary production environment, we also support the use of anti-microbial ingredients in formulas, as well as control of temperature, pH, and water activity, to reduce the possibility that *L monocytogenes* could grow in the product, if the organism were introduced inadvertently at low levels.

In Directive 10,240.3, FSIS properly recognized the inherent differences in the risk profiles between products that do not support the growth of *L. monocytogenes* and those that do. Indeed, the Directive places products that meet one of the following criteria in a low risk category:

Product that is stable with respect to growth of *L. monocytogenes* by any of the following means:

- Held at or below 0 degrees Centigrade
- pH < 4.5
- pH < 5.0 + refrigerated storage
- aw <0.90
- aw <0.92 + refrigerated storage
- aw <0.95 + pH <5.5
- The presence of an antimicrobial agent (e.g., lactate, diacetate) that has been validated through scientific studies to inhibit growth of *L. monocytogenes.*

The Directive also classifies products that undergo further processing after packaging, e.g., in-package heating, (thus eliminating the risk of post-process contamination) in the low risk category. The establishment choosing this option is required to substantiate the position that such products should be classified in the low risk category by providing validation data to FSIS. The FSIS decision to classify products differently for regulatory purposes based upon level of risk is firmly rooted in sound science.

Therefore, in the risk assessment model, we recommend that FSIS account for the inherent differences in the risk profile of products that do not support the growth of *L. monocytogenes*. Scenarios could be modeled that reduce the amount of product contaminated with *L. monocytogenes* and more importantly, considering the ubiquitous nature of the organism, reduce the level of *L. monocytogenes* in product at retail. This approach is consistent with the sound analysis FSIS applied when the Directive was developed.

Kraft is a strong advocate of aggressive environmental monitoring programs as well as seeking long-term technological solutions to eliminate the health threat of *L. monocytogenes*. For example, our work with lactate salts and sodium diacetate has been published in peer-reviewed journals (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(4): 651-658), shared with the USDA, and made available to the meat industry without restrictions through PURAC, America. This scientific information should be reflected in the final risk assessment. Kraft believes a regulatory environment that recognizes this important intervention strategy will improve public health by incenting more manufacturers to implement these formulation options or invest in research to develop new control strategies.

Assumptions used to develop risk assessment outputs

Kraft advocates a science-based approach to protecting public health. We believe the assumptions used to develop the model in this risk assessment represent a worse case scenario-that is, one reflecting an operation that has not implemented a well-designed and validated *Listeria* control program. Based on our years of *Listeria* control experience, we believe many of the assumptions used in the model should be modified to more accurately reflect the conditions encountered under a fully functional control program for *Listeria*. We have reviewed our *Listeria* control program with FSIS scientists and policy staff. As noted in our published work with lactate/diacetate formulations, microbial growth predictions must be based on inoculum level, product formula, and storage conditions. The model should recognize the importance of product formulation and not evaluate growth potential solely on the probability of contamination.

While we agree with using risk assessment methodology, we are concerned with several parameters that do not reflect industry practices in well-managed plants. Our data demonstrates that the duration of a contamination event is much shorter than the one-week used in the model and that a contamination event is much less frequent. We disagree with the incorporation of a mid-shift clean-up following an 8-hour production run. For years, industry has had effective Listeria control programs that have eliminated this high-risk practice to minimize product contamination. If sanitation were only 75% effective as modeled the facility would never be effectively cleaned and sanitized and in all likelihood product spoilage would be a serious problem for the site. Based on Kraft's historical data, sanitation effectiveness is closer to 99.99%.

We believe the model could be enhanced by independently adjusting all parameters for large, small, and very small plants. This modification would improve the accuracy of the model because the components of sanitation data, food contact surface testing, product testing, contamination event timing, duration and levels, transfer coefficient, food contact surface tested area and RTE sampled mass are different amongst these plant classifications. For example, large plants supported by a strong technical corporate infrastructure have the resources to validate the efficacy of their programs. As we noted above, sanitation effectiveness in a large operations such as those represented by our data is 99.99% effective, not 75%, which greatly changes the risk parameters of the model. These enhancements would further help quantify the improvement made by adoption of current industry best practices for Listeria control. The model would then appropriately weight the effectiveness of programs among plants of different sizes rather than making the assumption that all sanitation programs are equivalent.

Risk Assessment Outputs

Although Kraft shares the Agency's interest in promoting and expanding environmental testing among producers of RTE products, we are concerned about the potential impact of the draft risk assessment on the Final RTE Rule. Our scientific evidence would suggest that several of the outputs of the risk assessment should be reevaluated.

Output 1. Food contact surfaces found to be positive for *Listeria* species greatly increased the likelihood of finding RTE product lots positive for *L. monocytogenes*

Kraft does not agree that finding a positive data point on a contact surface greatly increases the likelihood of finding positive lots of finished product. Kraft data show that random positive results on contact surfaces are associated with low levels of *Listeria* (<10) that even potentially could be transferred to product. Our environmental monitoring data demonstrate that, 84% of the time, when a random positive food contact surface is observed, the site is negative when re-sampled. Additionally, Kraft is concerned that misunderstanding output 1 could result

in a proposal to increase finished product testing, which for a low frequency defect such as *Listeria* is statistically ineffective.

As noted in the risk assessment, the assumption that there is 75% probability of detecting a single *Listeria monocytogenes* cell in a product sample is contrary to published statistical sampling protocols. The International Commission for Microbiological Specifications for Foods (ICMSF) recently published Microorganisms in Foods 7: Microbiological Testing in Food Safety Management (2002) Kluwer Academic/Plenum Publishers, New York, NY which discusses the statistical probability of detecting low levels of microbial contaminants in production lots of various sizes. ICMSF sampling tables show that in a lot containing 2% positives; if three samples are taken there is a 94% chance of not detecting a positive and there is a 30% chance of missing a positive even when 60 samples of the lot are taken. These publications emphasize that microbiological contaminants are not uniformly distributed as suggested in the risk assessment but rather are randomly distributed. Additionally, our experience with *Listeria* control demonstrates that *Listeria* contamination is a random event, except of course if there is a chronic *Listeria* harborage site that has not been addressed successfully.

Output 2. Frequency of contamination of food contact surfaces with *Listeria* species appears to encompass a broad timeframe, and the duration of a contamination event lasts approximately a week.

The scenario used in the risk assessment based on the IDV investigation of a facility that had been associated with an outbreak of listeriosis does not represent a typical manufacturing scenario. Rather the risk assessment model makes assumptions that a *Listeria* contamination event occurs with a predictable frequency and duration. Kraft data does not support this assumption. Kraft Foods samples and analyzes greater than 100,000 product contact surface sites annually in its RTE meat, frozen pizza and cheese manufacturing operations and has data that runs counter to point 2. Data provided to the risk assessment team in the same format as the Tompkin data (Tompkin, R. B. 2002. Control of *Listeria monocytogenes* in the Food-Processing Environment. J. Food Protection 65(4): 709-725), indicates that *Listeria* contamination is a random event. 50% of the lines monitored by Kraft have no positive product contact surface samples. 84% of the lines that have positive contact surfaces samples are only positive as a single occurrence.

The only time there is any "broad timeframe of positives" is if there is a harborage site that might seed a processing line. The very purpose of an environmental sampling plan is to be sure that if such a condition develops, it is rapidly detected so that the corrective action may be taken and it is eliminated. In fact, the environmental plan that we utilize contains a corrective action of a "deep clean" which is designed to identify and sanitize any potential harborage site.

Additionally, Kraft has enumerated swabs from lines or the surrounding environment where positives have been detected and has found > 10 organisms per area swabbed only on floor sites (several square feet) or a niche (less than a few square inches). Environmental samples of product contact surfaces tested for *Listeria* that have been enumerated contained less

than the detection limit of the methods (direct plating on MOX and MPN). Based on research commissioned by Kraft and performed by Dr. Michael Doyle at the University of Georgia (UGA), which was presented to USDA on 11/15/02, there is little, if any transfer to finished product at the aforementioned low levels found on product contact surfaces. It is true that if there is no positive *Listeria* species found there is a great likelihood that none will be found in the finished product. Data presented by Dr. Doyle indicates that a random positive food contact surface event is not likely to result in transfer to finished product. Various deli meats were sliced on equipment purposely contaminated with *L. monocytogenes.* Dr. Doyle's work demonstrated that high levels of *L. monocytogenes* (> 1000 organisms per square inch) are required to be present for a significant measurable level of transfer resulting in positive finished product. Dr. Doyle intends to publish this study in a peer-reviewed journal. In the meantime, we respectfully submit that these data are more appropriate for use than the data from Midelet and Carpentier (2002) because the UGA study was specifically designed to evaluate deli meat and the slicing process, whereas the Midelet and Carpentier (2002) study was conducted with raw beef and used a 30 second contact time on an inoculated surface. Results shared with the USDA illustrate this position.

Low Inoculum	# Positive packages/# packages tested (4C storage)			
	Day 1	Day 30	Day 60	Total
Oven Roasted Turkey (Will support growth) Inoculum = 11 – 21 cfu/in^2	0/200	0/200	2/200	2/600

High Inoculum	# Positive packages/# packages tested (4 C storage)		
	Day 1	Day 30	Total
Hard Salami (Will not support growth) Inoculum = 1060 – 5850 cfu/in^2	9/200	1/200	10/400
Bologna (Will not support growth) Inoculum = 1100 – 1800 cfu/in^2	2/200	1/200	3/400
Oven Roasted Turkey – Trial 1 (Will support growth) Inoculum = 1420 – 1480 cfu/in^2	8/200	3/200	11/400
Oven Roasted Turkey – Trial 2 (Will support growth) Inoculum = 1080 – 4150 cfu/in^2	22/200	47/200	69/400

These results illustrate the sporadic nature of *Listeria* contamination even when an unrealistically high level of organisms is inoculated onto a product contact surface. Therefore, the modeling of transfer needs to be revised for a process that is under control

Output 3. The proposed minimal frequency of testing/sanitation of food contact surfaces presented in the proposed rule (66 FR 12589, February 27, 2001), results in a small reduction in the levels of *L. monocytogenes* on deli meats at retail.

We concur with output 3 given our comments on the proposed the FSIS proposed rule: *Performance Standards for the Production of Processed Meat and Poultry Products* (66FR 12589, February 27, 2001) regarding sampling frequency based on plant size. Our own internal experience has demonstrated the need to sample product contact surfaces weekly in order to maintain confidence in the effectiveness of the *Listeria* control program in place. This output is also consistent with the position the Agency took when it implemented Directive 10,240.3 on 12/9/02. Indeed, this output demonstrates the importance of conducting risk assessments to support policy decisions. The criticism the Agency received for not implementing the RTE Rule as written was unwarranted. The proposed frequency of testing would have had little impact on risk reduction as noted at the public meeting by the risk assessment team.

Output 4. Increased frequency of food contact surface testing/sanitation leads to a proportionally lower risk of listeriosis.

During discussions with the Agency regarding Listeria control strategies and Directive 10, 240.3 we emphasized that public health is best protected by implementation of a validated *Listeria* control program consisting of aggressive environmental monitoring, effective corrective actions, and incorporation of appropriate intervention technologies. Our experience indicates that weekly monitoring is necessary to maintain effective control of the post-processing environment thus minimizing the risk of contaminating product with *Listeria.*

Output 5. Combinations of interventions (e.g., testing/sanitation, pre-and post-packaging interventions, and growth inhibitors) appear to be much more effective than any single intervention in mitigating the potential contamination of RTE product with *L. monocytogenes* and reducing the subsequent risk of illness or death.

Output 5 reflects the multifaceted strategy we have used effectively to control *Listeria.* However, we do not view cycles of testing/sanitation as an intervention tool, because effective corrective actions must address the underlying root cause of positive results. Corrective actions may include, but are not limited to adherence to GMPs and SSOPs, equipment redesign and/or replacement, and employee training.

The modeling we have done on formulation interventions (Seman, et al 2002), shows efficacy of at least 99%, based on average total plate counts for RTE finished products at the time of packaging of less than 10 organisms per hot dog or slice of deli meat. The effectiveness of formulation interventions is also supported by other data shared previously with the risk assessment group, which show that if *Listeria* contamination were to occur, it would be at low levels.

If microbial contamination were to occur at these low levels, the formulation would limit growth. The modeling graphs in the publication illustrate the effectiveness of various intervention strategies using the aforementioned parameters. Log growth differences were observed with and without interventions that support the previously noted efficacy of 99% inhibition of *L. monocytogenes*.

Risk Assessments Impact on Public Health

Kraft is convinced that, as a matter of good manufacturing practice, all producers of RTE meat and poultry products must institute *Listeria* control programs that include an aggressive environmental testing component. The goal of environmental testing is to reduce the likelihood of finished product contamination. In order to accomplish this objective, aggressive testing programs must be designed to meet the unique challenges presented in every plant. The goal of an effective testing program must be to locate the organism in order to take the necessary steps to sanitize harborage sites and make corresponding process improvements to eliminate it. Kraft, therefore, shares the Agency's commitment to promoting environmental testing among producers of RTE products.

It has been repeatedly emphasized that environmental samples found to be positive for *Listeria* species *or L. monocytogenes* should be viewed as a "success" because the introduction of the pathogen is unavoidable in the processing environment and can be addressed most effectively by programs that identify and address its inevitable presence. The draft risk assessment, however, may cause manufacturers to design less aggressive sampling programs given its continued reference to test and hold sampling protocols.

Kraft is concerned that the draft risk assessment has not been peer reviewed nor modified to reflect actual industry practices or published scientific studies that would impact the conclusions of the risk assessment. Unless the assumptions of the risk assessment are modified, conclusions may be drawn that do not have the greatest impact on protecting public health.

Our experience with *Listeria* control, suggests the following modifications to the current assumptions in the FSIS model (% refers to log reductions):

- Overall sanitation efficacy is 99%-99.99% and enhanced sanitation efficacy is 99.999%-99.9999%

- Formulation intervention efficacy is 99% to 99.99%. Post-packaging lethality should be modified to reflect an efficacy of 99.99%-99.999%.

- Transfer of microorganisms to product occurs very infrequently. In studies at UGA, less than 6.0 % of 1600 packages exposed to the unexpectedly high levels of 1000 or more organisms during slicing were contaminated. Only 0.25% of the packages of oven-roasted turkey, which supports the growth of *L. monocytogenes* when exposed to a more realistic number of 10-20 organisms, were contaminated. These positive

samples were not detected after 30 days of storage but rather following 60 days of storage. Therefore, the modeling of transfer needs to be revised for a process that is under control.

- Conclusions drawn from finished product testing modeling should be recalculated based on the ICMSF lot sampling tables. Detection efficiency would be much less than the 75% used in the model. ICMSF sampling tables show that with a lot containing 2% positives, if three samples are taken there is a 94% chance of not detecting a positive, i.e., a 6% detection efficiency. The model considered only one sample per lot. Statistical calculations determine that with one sample taken in a lot with 2% positives, there is a 98% chance of not detecting a positive, i.e., a 2% detection efficiency.

- Our environmental monitoring data demonstrates that 84% of the time a positive food contact surface is observed it is a solely a sporadic event since the site is negative when re-sampled. Contamination events are much shorter and more infrequent than modeled in the risk assessment.

Summary

Kraft believes that public health is best protected by implementing a validated *Listeria* control program based on aggressive environmental monitoring, science based corrective actions, and the incorporation of appropriate intervention strategies. Success depends upon locating *Listeria*--**finding positive results**—and taking proper corrective action. Even with effective control, the manufacturing environment will not be completely *Listeria* negative. A regulation that fails to recognize this fact will not be effective in reducing the public health risk associated with *L. monocytogenes.* In addition, the draft risk assessment does not take into consideration product formulation and its impact on outgrowth of *L. monocytogenes*. Rather, factors in the model were manipulated to predict levels of *L. monocytogenes* at retail in sliced deli items that duplicated the consumption levels in the joint FDA/USDA *L. monocytogenes* Risk Assessment. (FDA and FSIS, 2001. Draft assessment of the relative risk to public health from foodborne *Listeria monocytogenes* among selected categories of ready-to-eat foods. www.foodsafety.gov/~gms/lmrisk/.html) Given the duration of time that has lapsed since the collection of the data upon which FSIS relied, it is unlikely that the risk estimates reflects the reduced risk of these product due to current application of various microbial inhibitors.

We recommend that the risk assessment team consider applying the modifications we have suggested to the model to improve the accuracy and reliability of the model outputs. Key to these modifications is our experience that *Listeria* contamination is a random sporadic event in the production environment based on the interpretation of hundreds of thousands of environmental samples taken during the past two decades. It is also essential given the impact of this risk assessment that it be subjected to a scientific peer-review process to validate the assumptions of the model.

Every manufacturer of ready-to-eat meat and poultry products should implement control programs for *Listeria,* consistent with current good manufacturing practices. In fact, we recommended the final RTE Rule should mandate aggressive environmental monitoring, building upon the current RTE directive. The programs should begin with an effective lethality step and include aggressive environmental testing as well as the other fundamental components of a broad based *Listeria* control plan, such as systems to assure that the equipment and facilities are designed and maintained for effective sanitation, the use of traffic patterns that limit the ability of bacteria to spread from room to room, careful monitoring of employee practices, use of sensitive detection methods, etc. Broad based, aggressive programs are the most effective way to identify harborage sites for the organism, so that corrective and preventative actions can be implemented to sanitize the environment and reduce the risk of product contamination.

Thank you for this opportunity to provide comments on the FSIS Draft Risk Assessment for Listeria in Ready-to-Eat Meat and Poultry. Please do not hesitate to contact me if Kraft can provide additional information or support to this important FSIS effort.

Very truly yours,

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