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FSIS

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Subject: Feedback regarding the FSIS Listeria Risk Assessment Public Meeting

As a follow-up to our discussions last week regarding the public meeting and Kraft's listeria control strategy, Dr. Elsa Murano recommended that we forward you a brief summary of our suggestions that we believe would help strengthen the reliability of the draft risk assessment model. These suggestions are based on the research data we have previously shared with the Agency and our own practical experience in the environmental control of listeria. Of course, none of these data apply in cases where there is a chronic listeria harborage site that has not been addressed.

Specific issues we agreed to address from a practical industry perspective include:

Share information on the actual size of areas swabbed in a typical environmental sampling program.

Typical industry environmental sampling programs including Kraft's rely on biased intensive sampling during production rather than pre-operational. The sampling approach is biased because likely sources of listeria are evaluated. Large surface areas are sampled generally representing at a minimum of 40 square inches up to 200 square inches/sample site. Therefore, a minimum of 3 to 5 square feet is sampled during routine monitoring. However, it is important to note that significant variation in surface area sample can exist. This is driven by the biased nature of sampling site selection to specific areas more likely to be harborage sites.

Describe current industry sampling rates, weekly composite sampling breakdown or individual sites.

Kraft randomly samples each RTE manufacturing line on weekly basis varying the day of the week and shift. We use composite samples of the production line that vary from a minimum of five to ten sites into one or two composites of each RTE production line. Weekly monitoring of all RTE production lines is a typical industry (among large plants) practice. In addition, non-contact surfaces are monitored at a similar frequency. Because the sampling plan is biased, the results provide sound evidence that negative results indicate that process control has been achieved. We also conduct additional sampling in response to positive results to verify the effectiveness of corrective actions designed to address the issue.

We suggest the risk assessment team consider applying the following modifications 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 thousands of environmental samples taken during the past two decades.

1. Our experience demonstrates that sanitation efficacy is 99.99%. This value is based on a review of the results of validation studies performed on all RTE productions lines. The percentage was determined by evaluating the semiannual validation results for all RTE meat-processing lines within Kraft, (approximately 110 lines).

2. Our experience with modeling the efficacy of formulation interventions indicates that the efficacy is 99%. Please refer to the article previously forwarded (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) that verifies this intervention efficacy value. This statement is based on the fact that current average total plate counts levels for RTE finished products at the time of packaging are less than 10 organisms per hot dog or slice of deli meat. Additional data supporting this position that if listeria contamination were to occur, it would be at low levels was shared with the risk assessment group. This data showed that random positive contact surfaces contain few listeria (<10) that can be transferred to product.

   If contamination were to occur, it would be at such low levels of microorganisms that may potentially contaminate RTE products at the point of packaging, the formulation intervention discussed is 99% effective because growth is limited. 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*.

3. Based on the 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 will 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 done 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				
	Day 1	Day 30	Day 60	Day 90	Total
Oven Roasted Turkey (Will support growth) Inoculum = 11 – 21 cfu/in^2	0/200	0/200	2/200	0/200	2/800

High Inoculum	# Positive packages/# packages tested		
	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.

4. As noted at the public meeting, 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 with 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. Our experience with listeria control demonstrates that listeria contamination is a random event.

5. 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. Again the data we shared with the risk assessment team does not support this assumption. Data provided to the risk assessment team in

the same format as the Tompkin data repeatedly referenced by the team 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. In the data presented to the USDA on 11/15/02 regarding repetitive environmental positive samples detected during routine weekly monitoring on a line, only 0.12 % were found to be positive in the third sampling following the corrective actions. 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 exists, it is detected so that the corrective action may be taken and it is eliminated.

Please contact me if you have any question regarding these suggestions for incorporation into the listeria risk assessment. We would be happy to share our experience with the risk assessors on formatting the data we have in a way that it can be incorporated into the risk assessment. As we have discussed, public health is best protected by implementing a validated *Listeria* control program founded on aggressive environmental monitoring, science based corrective actions, and the incorporation of appropriate intervention strategies. The current RTE directive, 10,240.3 accomplishes this goal and could be strengthened by mandating that manufacturers implement a listeria control program.

In summary we suggest the following modification to the current assumptions in the model (% refers to log reductions).

As seen in point #1 sanitation efficacy is 99%-99.99% and enhanced sanitation efficacy is 99.999%-99.9999%

As seen in point #2 formulation intervention efficacy is 99% to 99.99% and post-packaging lethality efficacy is 99.99%-99.999%

As seen in point #3, based on current research, transfer of microorganisms to product occurs very infrequently. Less than 6.0 % of 1600 packages exposed to 1000 or more organisms during slicing were contaminated. Therefore, the modeling of transfer needs to be revised for a process that is under control

As seen in point #4, conclusion drawn from finished product testing modeling should be recalculated based on the ICMSF lot sampling tables. Detection efficiency would be much less than 75%. Even with 60 samples the tables predict that 30% of the time a positive lot would not be detected.

As seen in point #5, 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.