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Foodmaker Inc. Proposal for Validation of Intervention Technologies Ability to Remove/Destroy Pathogens (*E. coli* O157:H7) from Beef Carcasses on the Slaughter Floor

Microbiological testing, by itself, is not a control point in any operation. Microbiological testing can be utilized as a monitoring program to validate that a process is under control. Finished product testing on ground beef can provide limited results regarding the ability of the grinding process to control the microbial contamination. However, because of the constraints of time, finished product testing on ground beef has limited ability to provide input for corrective action at the point of contamination, which occurs during the dressing and fabrication of the beef carcass. The only options for corrective action when doing finished product sampling and testing include destruction of contaminated product (finished ground beef), coupled with removal of raw material suppliers (beef trimmings) from the system who continue to provide contaminated products. Therefore, in conjunction with our finished product serial sampling program, we also sampled 2000-pound combo bins to test for the presence of *E. coli* O157:H7.

In the spring of 1998, we saw an increased incidence of finished product testing positive for *E. coli* O157:H7. These finished products were produced using meat from prescreened combo bins. Beginning 12 September 1998, the rate of samples detected to be positive for *E. coli* O157:H7 during the fall season was also elevated over previous years. In November 1998, Foodmaker personnel began discussions with its suppliers regarding the testing of samples from carcasses to detect the presence of *E. coli* O157:H7.

The use of multiple interventions in the slaughter facility is designed to reduce and/or eliminate the pathogenic bacteria from the carcass. We determined that it would be beneficial to monitor carcasses as a means to validate process control systems during slaughter and fabrication at the point where potential contamination may occur. When carcasses are determined to be positive for the organism in question the carcass may be removed from the raw meat processing chain, and corrective action may be immediately taken on the intervention steps in place to ensure that they remain effective in controlling contamination.

Sampling and testing of carcasses was viewed as a more desirable alternative to combo bin sampling and testing because of the ratio of the surface area at risk to be contaminated to the remainder of the combo bin made finding contaminated meat samples extremely difficult. Based upon data that was available to us for 50:50 fat trim, we calculated that the portion of the combo bin that was the surface area most at risk was only 0.374% (surface area at risk = .27 lbs., cattle per bin = 27.7). Removing a 75g sample per combo bin would result in a one in 3 million chance of finding the area at risk, not the organism itself.

The purpose of sampling and testing is to reduce the risk of exposure to consumers in both the retail and foodservice industry in ground beef products. It was our desire to recommend and validate a means by which the testing of carcasses might provide a level of vigilance for which all users of the boneless beef raw materials may be assured that the "hot spots" of contamination are detected. Foodmaker Inc. will not abandon the serial sampling program that is currently in place for finished products. At a recent gathering by the AMSA in Kansas City, it was determined that a program such as ours has a 95% confidence level of detecting hot spots of contamination, that is detecting more than 1 cell in 500g of product. It is our belief that a validation of intervention steps would make the entire industry safer, and would benefit Foodmaker Inc. by reducing the number of positive results we detect in samples from finished products.

For testing to be effective, a large surface area on the carcass must be sampled to avoid missing the organism with small swabs or excisions. Published research has been unable to detect the organism on carcasses. It has been reported by industry sources that the organism has been found on carcasses at the frequency of between 1 in 1000 and 1 in 1500 tests. This information is based on relatively small sample sizes and standard ELISA assays used for screening. There have not been a large number of tests conducted considering the number of animals slaughtered each day. We believe that the lack of detection on the carcasses by researchers may be due either to small numbers tested, or testing methodology.

It is our belief that the method of sampling the carcasses for the presence of *E. coli* O157:H7 must be addressed by a pilot study. We have proposed taking a large swab, approximately 15cm wide, from the hind-shank to the neck, down the midline of the carcass, and over the fore-shank. This proposed method would sample a large portion of the surface area of the carcass most at risk to be contaminated with the organism. Communications with members of the industry indicate that most "in-house" labs can handle between 10 and 20 pre-enrichments per day. Sample compositing would be accomplished so that the labs within the slaughter/fabrication facility could do all of the lab work, and no samples would need to be sent to outside laboratories.

The method of assaying the samples must be a rapid procedure that has a high sensitivity for *E. coli* O157:H7, such as the Polymerase Chain Reaction (PCR/DNA) BAX method from Qualicon. In-house testing is crucial to have results of microbiological testing prior to carcasses being released for fabrication. The PCR will provide rapid results, allowing corrective actions to be taken prior to carcasses being released for fabrication. The assay procedure requires 18 to 24 hours of pre-enrichment prior to testing. This assay has been shown to be 5 to 10 times more sensitive than current ELISA based techniques. Carcasses would be sampled following the application of the last intervention step used on the kill floor, while the carcass is still wet, facilitating the collection of the sample.

There is some controversy regarding the sampling frequency. Sampling rates should be determined by three factors: 1) the ratio of surface are at risk to remainder of the combo bin, 2) the ability of the facility to sample and enrich samples (including determination of an acceptable composite size), and 3) the level of vigilance desired. Point number 3 may be the area that will create the most controversy. We propose a similar level of vigilance to that we currently have with our finished product testing. Research conducted by Colorado State University for the National Cattleman's' Beef Association has identified the areas on the carcass, which contain the highest number of microbial contaminants. It will be necessary to determine the amount of surface area, from these areas that needs to be sampled to provide some level of statistical confidence for detection of the organism. Further, it is necessary to determine the amount of trim surface area from carcasses that are represented in a combo bin. This data is required for each type of combo bin (e.g. 50's, 85's, 90's, 95's etc.). This data will be used to determine the number of cattle required for sampling and testing to assure that no more than 1 cell is present in 500 g of finished ground beef product at a 5% incidence.

It will be important to assure that the sampling and testing protocol used is truly effective at detecting the organism on the carcass. Therefore it is important to implement a small pilot study, which will involve intensive testing for a short period of time. Our goal was to collect upwards of 2000 samples and show that *E. coli* O157:H7 can be detected on the carcass. Since the goal of the pilot study is to detect a contaminated carcass, it would be beneficial to test both pre- and post intervention. Positive results would verify the sampling and testing methods are effective, and the expected reduction in the levels of *E. coli* O157:H7 would validate the efficacy of the intervention technologies. The study should be conducted at the time of year that the organism is at its' highest prevalence, in an area where the organism is most prevalent.

The use of intervention technologies such as steam pasteurization, hot water pasteurization, steam vacuuming, and organic acid rinses used in conjunction can create multiple hurdles which reduce the bacterial contamination on the carcass. It is imperative that the use of multiple interventions be installed in all slaughter facilities to reduce the amount of bacterial contamination in finished raw materials used for further processing and grinding. The most efficient use of these interventions should be discussed by all parties, resulting in guidelines for the industry that would allow more uniform application of these

technologies. We believe that all slaughter plants should have a minimum of three intervention steps, one immediately following hide removal and two-post evisceration (one being a validated thermal processing treatment such as hot water or steam pasteurization). It is the use of these interventions that ensure clean, safe product, not the testing of product. Testing for *E. coli* O157:H7 after the slaughter process and prior to fabrication provides a validation of slaughter process control, which includes GMP's, SOP's HACCP and validated intervention technologies.

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Foodmaker Inc.

Date	Produc	COMPOS	E coli 0157:H7		TPC	OLIFOR	E COLI	AUREU	OCYTOG
			45	1	1,702	46	10	13	
					10,000	320	20	50	
10/1/98	10*1	08-11	No	0	1000	30	9	9	neg
10/1/98	10*1	12 to 14	No	0	1000	10	9	9	neg
10/1/98	4*1	14-15	No	0	2000	10	9	9	neg
10/1/98	4*1	16-19	No	0	1000	130	10	9	neg
10/1/98	4*1	20-23	No	0	4000	200	9	9	neg
10/1/98	4*1	00-03	No	0	2000	10	9	9	neg
10/1/98	4*1	0:04	No	0	99	50	9	9	neg
10/3/98	10*1	07 to 10	No	0	10000	120	9	9	neg
10/3/98	10*1	11 to 14	No	0	3000	20	9	9	neg
10/3/98	4*1	14-17	No	0	7600	320	9	9	neg
10/3/98	4*1	18-21	No	0	200	120	9	20	neg
10/3/98	4*1	22-01	No	0	2100	110	10	10	neg
10/3/98	4*1	02 to 04	No	0	2200	110	9	9	neg
10/7/98	4*1	07 to 10	No	0	99	20	9	10	neg
10/7/98	4*1	11 to 14	No	0	99	20	9	10	neg
10/7/98	4*1	15-18	No	0	99	10	10	9	neg
10/7/98	4*1	19-22	No	0	99	40	9	9	neg
10/7/98	4*1	23-02	No	0	1000	30	9	40	neg
10/7/98	4*1	03 to 04	No	0	6000	70	9	10	neg
10/15/98	4*1	07 to 10	No	0	3000	30	9	10	neg
10/15/98	4*1	11 to 14	No	0	99	100	9	30	neg
10/15/98	4*1	15-18	No	0	1000	10	9	50	neg
10/15/98	4*1	19-22	No	0	4000	40	9	30	neg
10/15/98	4*1	23-02	No	0	99	9	9	10	neg
10/15/98	4*1	03 to 04	No	0	1000	10	9	20	neg
10/22/98	10*1	08 to 11	No	0	7000	30	10	9	neg
10/22/98	10*1	12 to 13	No	0	99	9	9	9	neg
10/22/98	4*1	13-15	No	0	1000	10	10	9	neg
10/22/98	4*1	16-19	No	0	2000	50	20	9	neg
10/22/98	4*1	20-23	No	0	99	10	9	9	neg
10/22/98	4*1	00-03	No	0	1000	10	9	9	neg
10/22/98	4*1	4	No	0	2000	9	9	9	neg
10/27/98	10*1	07-10	Yes	1	999	20	20	30	neg
10/27/98	10*1	11-12	No	0	999	9	9	10	neg
10/27/98	4*1	12-15	No	0	1000	9	9	20	neg
10/27/98	4*1	16-19	No	0	1000	300	9	10	neg
10/27/98	4*1	20-23	No	0	999	100	9	9	neg
10/27/98	4*1	00-03	No	0	1000	10	10	9	POS
10/27/98	4*1	04	No	0	999	9	9	20	neg
10/29/98	4*1	07 to 10	No	0	1000	10	9	9	neg
10/29/98	4*1	11 to 14	No	0	99	30	9	9	neg
10/29/98	4*1	15-18	No	0	99	9	9	9	neg
10/29/98	4*1	19-22	No	0	99	20	9	9	neg
10/29/98	4*1	23-02	No	0	99	9	9	9	neg
10/29/98	4*1	03 to 04	No	0	99	40	9	10	neg

NES	SALMONELLA	
1		-
0	neg	0
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1	neg	0
0	neg	0
0	neg	0
0	neg	0
0	neg	0
0	neg	0
0	neg	0
0	neg	0

Supplier 2 Micro Records FY99

	Month	E coli 0157:H7		n	TPC	COLIFORM	E COLI	S AUREUS	SALMONELLA	
Total	Avg	1,395	4	280	2,220	44	16	13		13
	Max	0.29%			16,000	1,210	580	380	4.64%	
AVG	Sep-98	42	-	8	2,325	38	9	15		-
	Oct-98	210	3	42	2,957	62	17	13		3
	Nov-98	232	1	48	2,340	55	28	14		2
	Dec-98	393	-	82	1,935	54	18	16		8
	Jan-99	302	-	60	2,052	40	15	10		-
	Feb-99	216	-	40	1,713	17	11	12		-
	Mar-99									
	Apr-99									
	May-99									
	Jun-99									
	Jul-99									
	Aug-99									
	Sep-99									
MAX	Sep-98				5,600	90	10	60		
	Oct-98				12,400	870	200	160		
	Nov-98				10,000	620	580	100		
	Dec-98				16,000	1,210	310	380		
	Jan-99				13,600	1,000	80	40		
	Feb-99				7,600	90	90	40		
	Mar-99									
	Apr-99									
	May-99									
	Jun-99									
	Jul-99									
	Aug-99									
	Sep-99									

Riley, Mary

From: Engeljohn, Daniel
Sent: Tuesday, March 23, 1999 6:48 AM
To: Riley, Mary; Powell, Mark
Subject: FW: E. coli O157:H7 test results

Sensitivity: Personal

Maryann, please print each file and formally log all the information as one comment from Foodmarker, Inc. Since the e-mail came from Mark Andersen, use his name as commenter. Also, file the comment so that page 1 begins with the letterhead. FYI, the two file with ATT extensions do contain information about the encoding for the Excel charts; if you cannot access, I will give you a copy, but they are not necessary for the administrative record.

cc: Mark Powell

DANIEL L. ENGELJOHN, Ph.D.
Director, Regulations Development and Analysis Division
Food Safety and Inspection Service, USDA
- Phone--(202) 720-5627
- Fax--(202) 690-0486
- E-mail--daniel.engeljohn@usda.gov

-----Original Message-----
From: mark.andersen@foodmaker.com [SMTP:mark.andersen@foodmaker.com]
Sent: Monday, March 22, 1999 8:59 PM
To: Daniel.Engeljohn@dchqexs1.hqnet.usda.gov
Cc: david.theno@foodmaker.com; darren.blass@foodmaker.com
Subject: E. coli O157:H7 test results
Sensitivity: Personal

I have included all of the data I have available for you regarding E. coli O157:H7 testing. Some of this data may have been sent to you by AMI, however I will re-send the data so that you have it at your disposal. The finished product data is from two different sources. It is slightly different in presentation, and data collection. For the purpose of statistical analysis, <10 was entered as 9, <100 as 99 and <1000 as 999.

Data 1 is taken from patties removed every 15 minutes from the production line. These patties are composited into a sample that represents four hours of production. Microbiological testing is done on each composite (TPC, Coliforms, E. coli, S. aureus, Salmonella, L. monocytognes, E. coli O157:H7).

Data 2 is taken from the grinder head, beginning middle and end of each 3000 lb. batch. 25 g from each are composited into one 75g sample per batch. Each batch is analyzed for E. coli O157:H7. Half shift composites are made to assay for the remainder of the microbiological profile (TPC, Coliforms, E. coli, S. aureus, Salmonella).

Also included are the results of the testing of raw materials for hamburger patty production from each vendor. The data includes, but is not exclusive to, production of our products. Loads are quartered, and each combo bin is sampled. Thirteen pounds of product is removed from each 2000 lb. combo bin, either by grab or core methodology. From this 13 pound ground sample, a total of three separate 25 gram samples are pulled from three separate points in the sample. These three 25 gram samples are combined to make the 75 gram composite that is required from each combo bin. The five 75 gram samples from each of the combo bins within a sublot are combined to produce the 375 gram sample that is the analytical testing unit.

Between our 2 suppliers, there were 5 documented cases in which a partial load was positive for E. coli O157:H7, but the remaining sublots were not positive, and thus used for production. Some of this product was produced into product for us, and thus was finished product tested. None of the finished product tested was positive for the organism. Not all of the sublots were used for our products, and thus were not subject to finished product testing.

Summary of Results of E. coli O157:H7 Combo Bin Testing (supplier 2)

	# of Tests	Presumptive Positives	% Presumptive	Confirmed Positive	% Confirmed
Total	6,640	31	0.467%	12	0.181%
50:50 trim	4,708	27	0.573%	9	0.191%
Lean (90's/85's)	1,932	4	0.207%	3	0.155%

Also included are our comments in reference to the proposal by AMI.

(See attached file: Micro1.xls)(See attached file: Micro2.xls)(See attached file: FMIComments.doc)

(UUEncoded file named: Micro1.xls follows)
(Its format is: Excel 2.x Chart)


Micro1.xls


ATT01906.ATT


Micro2.xls


ATT01907.ATT


FMIComments.doc