July 18,2001

FSIS Docket Clerk
Docket No. 00-048N
U.S. Department of Agriculture
Food Safety and Inspection Services, Room 102, Cotton Annex
300 12th St., S.W.
Washington, DC **20250-3700**

Re: Relative Risk to Public Health from Foodborne *Listeria rnonocytogenes* among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document and Risk Management Action Plan; Docket No. 99N-1168, 66 FR 5515.

Dear Sir or Madam:

1. Introduction and General Comments

The Milk Industry Foundation (MIF) appreciates the opportunity to comment on the above-referenced draft risk assessment and joint action plan prepared by the Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS). MIF is the trade association for manufacturers, processors, distributors and marketers of milk and milk products. Its 109-member companies process approximately 90% of the milk and milk products manufactured in the United States. **MIF** is one of the constituent organizations of the International Dairy Foods Association.

MIF advocates a science-based approach for assessing the risk of ready-to-eat foods. We support cooperative efforts among government, industry, and consumers to enhance food safety, and prioritization of food safety challenges according to science-based assessments of consumer risk. Accordingly, we applaud the agencies' efforts to evaluate the risks posed by ***Listeria monocytogenes*** using a science-based analysis.

MIF showed it's commitment to the risk assessment effort by conducting a Market Basket Survey funded by MIF companies to obtain current data on contamination frequency and levels of ***L. monocytogenes*** in pasteurized milk at retail. This provided FDA with scientific data and information for the risk assessment and addressed the impact that foodborne ***Listeria monocytogenes*** can have on public health.

2. MIF Survey of Pasteurized Milk at Retail in the United States for *Listeria monocytogenes*

MIF conducted this survey because there was a lack of recent data on the prevalence of ***Listeria monocytogenes*** in pasteurized milk in the United States. Pasteurized milk near code date in gallon, half-gallon, quart, pint and half-pint containers (paperboard and plastic) was collected from retail locations in four FoodNet cities (Baltimore, MD; Atlanta, GA; Minneapolis/St.Paul, MN; and San Francisco, CA). Milk samples were arranged in such a way that results were not traceable to specific brand name or manufacturer. Sampling occurred during a 5-week period from June 5 to July 8,2000 and included large and small retail stores in urban and suburban locations. ***L. monocytogenes*** was prescreened in samples through the AOAC approved rapid VIDAS ELFA method. Positive prescreening samples were cultured according to the Bacteriological Analytical Methods (BAM) and samples were enumerated by the Most Probable Numbers (MPN) technique and confirmed by biochemical characterization. The frequency of isolation and confirmation of L. ***monocytogenes*** was 0/1897 ***(0%)*** whole milk, 1/1846 (0.05%) nonfat milk, 0/1669 (0%) chocolate milk (various fat levels), 0/107 (0%) other milk samples (reduced fat and low fat milk). Overall, ***L. monocytogenes*** was confirmed in 0.018% of pasteurized milk samples (1/5519). Enumeration of the single confirmed positive sample in nonfat milk (1-gallon plastic container) resulted in ***L. monocytogenes*** at <0.3 MPN/g of nonfat milk at 5 days past code date.

The results of the MIF Survey show that contamination from ***L. monocytogenes*** is extremely rare in pasteurized milk. Additionally, results showed the level of L. monocytogenes found in the single positive sample was low (<0.3 cfu/g), even 5 days past the code date.

3. Post Retail Growth Concentrations

MIF believes that the estimated Exponential Growth Rate was inaccurately used to determine contamination levels of pasteurized milk. At MIF's request, Novigen Sciences assessed the impact of at-retail concentrations in pasteurized milk for which FDA used a growth factor to account for potential growth between production and retail, resulting in values of 0.04 cfu/g rather than 0.7 cfu/g. The same two-stage intake estimation approach used by FDA-FSIS was implemented and the distributions were then re-fit using only the U.S. data, adjusting the scale parameter only.

The exposure model was run using 1,000 population iterations and 100 uncertainty iterations and the estimated per-serving intakes were added to the dose-response model for the intermediate population. This was done to estimate the annual number of listeriosis deaths and serious listeriosis illnesses associated with each

food group and corresponding ranks, as well as the number of serious per-serving listeriosis illnesses and associated ranks.

The estimated risks and associated ranks are compared to the estimated risks and rankings derived by FDA-FSIS in Table 1, The per-serving risk (number of listeriosis illnesses) estimated by FDA-FSIS in the case of pasteurized milk is 4,000 times higher than that estimated using the "unadjusted' concentration data. ***The recalculated relative rank for pasteurized milk changed from 10 to 18 on a per serving basis, and from 3 to 17 on a per-annum basis.***

These findings highlight the importance of making accurate assumptions for growth of ***Listeria monocytogenes*** in milk.

4. Use **of** Foreign Data versus U.S. Data

FDA-FSIS found that there were enough sufficient differences between milk data in North America and milk data from other countries to warrant that the North American data was a more reliable measure for the frequency of ***Listeria monocytogenes*** contamination in milk. However, since insufficient quantitative data were available from the North American studies, FDA-FSIS used contamination levels from international data to estimate the variability in the distribution. However, it is important to note that very little, if any, pasteurized fluid milk manufactured outside the U.S. boarder is imported for direct consumption. IDFA correspondence to FDA stated that the level of imported milk, under **6%** milkfat, was **0.03%.** We believe that FDA stating this value as "less than 1% of milk consumed in the U.S. is imported misrepresents the actual figure. Additionally due to the restrictions on the U S . Cooperative Milk Safety Program, only Puerto Rico is approved to ship fluid pasteurized milk to the U.S.

It is important to point out that foreign processing conditions, such as pasteurization time and temperature, equipment design and sanitation requirements may differ greatly from U.S. standards. These processing differences are reflected in a higher contamination level for foreign processed milk. We question the validity of including concentration data from countries such as Argentina, Brazil, Czechoslovakia, Germany, Turkey or Poland.

5. Use **of Current** Data Compared to Pre **1993** Data

FDA-FSIS's assessment compared the data in studies published before and after **1993** (some of the studies published post **1993** included data collected earlier). For instance, data on pasteurized milk from Kozak, et. al. **(1996)** are for samples collected in the late 1980's. It is important to properly reflect when the data was collected.

We agree with the findings that contamination of pasteurized milk post **1993** dramatically decreased, most likely due to industry's implementation of improved control methods for the preventing post pasteurization contamination. This trend can be seen when comparing Kozak, et al, contamination frequency (0.61%- 1987) to IDFA's survey data that found a lower level of contamination (0.018%-2000).

6. Predictive Risk Ranking

As mentioned earlier, MIF believes the recalculated predicted risk of 18th per annum serving and 17th per annum serving for the intermediate population correctly characterizes this food category of pasteurized milk. We understand that the risk assessment explains the original rankings of pasteurized milk in close proximity to unpasteurized milk due to the large serving size and the higher degree of uncertainly found in the pasteurized milk data, However, in a practical sense, it appears that the ranking risk assessment model overstates the risk of pasteurized milk especially on a per annum basis since it has long been known that pasteurization of milk is an effective method of killing pathogenic bacteria and improving food safety.

7. Risk Management

The milk industry recognizes the seriousness of *L. monocytogenes* as a foodborne human pathogen. The milk industry has made extensive efforts over the past few decades to minimize any potential post-pastuerization contamination. The dairy industry worked in cooperation with FDA to develop "Recommended Guidelines for Controlling Environmental and Product Contamination in Dairy Plants" which was released in 1986. These guidelines have been successfully used in combination with strict adherence to basic sanitation principles, good manufacturing practices, and are also part of our industry's prerequisites for a dairy product HACCP program. This initiative successfully lowered the frequency of *L. monocytogenes* found in dairy plant environments and finished products. Recent data showed a significant decrease in contamination frequency when compared to pre 1993-data.

Additionally we are hopeful that in the immediate future new scientific information from the risk assessment will be used to set priorities for enhancing the safety of foods. FDA should reduce its inspection and testing focus on products that present a miniscule risk to public health. In addition, we strongly suggest that the information collected by the risk assessment be used by the FDA for determining health hazard evaluations for the purpose of food recall classifications.

8. Conclusion

MIF supports the efforts of FDA in consultation with the USDA Food Safety Inspection Service in conducting a **risk** assessment to determine relative risk of public health from ***Listeria rnonocytogenes.*** MIF firmly supports science-based risk

assessments as the most intellectually sound approach to addressing the risks of foodborne illness and encourages the continued use of such assessments. We urge the agencies to utilize this important scientific information to dictate future risk management priorities and reevaluate current regulatory policy.

MIF appreciates the opportunity to share our views on the risk assessment and action plan for the prevention of foodborne listeriosis. The MIF commends FDA and FSIS for leading the debate on this important public policy issue. **We** look forward to working with the agencies on the development of scientifically based policies founded on **a** thorough and complete assessment of the risks posed by ***Listeria monocytogenes*** in the food supply. Please contact me if you have any additional questions of if further clarification is necessary.

Yours truly,

Cary Frye

Cary P. Frye
Vice President
Regulatory Affairs

TABLE 1

IMPACT OF USING UNADJUSTED CONCENTRATION DATA FOR PASTEURIZED MILK ON THE ESTIMATED RISK FOR THE INTERMEDIATE POPULATION

FOOD GROUP	Estimated Median Number of Listeriosis Cases per Serving		Per-serving Relative Ranking		Per-Annum Relative Ranking	
	FDA	Scenario I1	FDA	Scenario I	FDA	Scenario I
SMOKED SEAFOOD	5.3E-08	5.1E-08	3	3	6	5
Raw Seafood	5.6E-10	5.3E-10	14	13	17	16
Preserved Fish	7.5E-09	6.4E-09	7	7	13	13
Cooked Ready-to-Eat Crustaceans	1.2E-08	1.1E-08	6	6	9	8
Vegetables	4.1E-11	4.0E-11	17	16	11	10
Fruits	1E-11	1.4E-11	18	17	16	12
Soft Mold-Ripened and Blue-Veined Cheese	2.5E-09	2.5E-09	9	9	14	14
Goat, Sheep and Feta Cheese	5.6E-11	5.8E-11	16	15	18	18
Fresh Soft Cheeses	5.8E-08	5.8E-08	2	2	7	6
Heat-Treated Natural Cheese and Processed Cheese	3.3E-10	3.3E-10	15	14	10	9
Aged Cheeses	3.2E-13	2.8E-13	19	19	19	19
Pasteurized Fluid Milk	**1.6E-09**	**3.8E-13**	**10**	**18**	**3**	**17**
Unpasteurized Fluid Milk	1.1E-09	1.0E-09	11	10	15	15
Ice Cream/Frozen Dairy Products	1.2E-13	1.1E-13	20	20	20	20
Miscellaneous Dairy Products	8.7E-10	8.0E-10	12	12	5	4
Frankfurters	5.9E-09	5.9E-09	8	8	4	3
Dry/Semi-Dry Fermented Sausages	8.1E-10	9.1E-10	13	11	12	11
Deli Meats	2.6E-08	2.5E-08	4	4	1	1
Pâté and Meat Spreads	6.6E-08	6.4E-08	1	1	8	7
Deli Salads	1.4E-08	1.4E-08	5	5	2	2

⊥ In this scenario, the concentration levels for the samples collected pre-retail were not inflated by assuming an 0.25 log growth model, as in **FDA's** assessment.

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