Kraft Foods

June 8, 2000

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USDA/FSIS Hearing Clerk
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, DC 20250-3700

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Jean Spence

Re: Revised Action Plan for the Control of *Listeria monocytogenes* for the Prevention of Foodborne Listeriosis, 65 Federal Register 26563, May 8, 2000

Dear Sir/Madam:

Kraft Foods, Inc. is the leading food manufacturer in the U.S., producing over 7.5 billion individual packages of food a year, with annual sales of over $17 billion. Kraft products are sold under well-known brand names – such as Oscar Mayer, Tombstone, Kraft, Maxwell House, and Post – that are found in almost every American home. The safety of our products and of our brands, whether regulated by the Food Safety and Inspection Service (FSIS) or the Food and Drug Administration (FDA), is of paramount importance to Kraft. Accordingly, Kraft has a very substantial interest in the implementation of effective programs that will assure the continued safety of all food products.

Kraft appreciates the opportunity to comment on the FSIS revised action plan for the control of *Listeria monocytogenes* for the prevention of foodborne listeriosis. We support the President's challenge to cut the number of foodborne illnesses in half by 2005.

GENERAL COMMENTS

While we recognize that listeriosis is a serious disease, we also recognize that certain foods do not provide the opportunity for its growth and, therefore, are not at high risk. We encourage the agency to maximize the use of its resources by focusing on products that present the highest risk: those that support the growth of *L. monocytogenes*. Compliance efforts should *not* focus on frozen foods (especially if they are heated prior to consumption), foods with barriers to growth of *L. monocytogenes* (pH, a_w or additives demonstrated to inhibit growth of the organism in the product), or foods that are given a listericidal process in the package and distributed without being repackaged. Serious consideration must be given to the results of the joint FDA/USDA risk assessment on *L. monocytogenes* in ready-to-eat (RTE) foods in focusing the agencies' compliance efforts.

To assure the success of the intensified effort to prevent foodborne listeriosis, the agency's action plan must be flexible, not rigid. Due to the ubiquitous nature of *Listeria* spp, adequate control usually involves an aggressive program of sanitation and process improvements, which are directed and measured by rigorous environmental monitoring. Kraft knows from long experience, however, that rigid programs prescribing generally applicable control measures, sampling protocols, and testing frequencies simply will not accomplish the objective. Instead, programs that work are designed to reflect the specific attributes of the product, process, equipment, facility, and employee practices used in each particular establishment. Moreover, when investigation is necessary due to positive findings, the fundamental program must be adapted and redirected immediately based upon the facts of the particular situation.

As we continue to improve our environmental monitoring programs, we drive through the entire organization the understanding that the primary goal is not to have perfect records, but to demonstrate success in effectively controlling the organism. Our experience indicates that it is counter-productive to inflict punishment for an effective self-audit program, which necessarily means one that reveals deficiencies on occasion.

At Kraft, environmental monitoring is one of the prerequisite programs that form the foundation for our SSOP and HACCP programs. We recommend that FSIS continue to permit manufacturers to manage environmental monitoring as a prerequisite program. Nevertheless, although changing the regulatory classification for the program will not make it more effective, we acknowledge that FSIS seems to be looking for suggestions on a different regulatory control scheme.

If FSIS concludes for any reason that the prerequisite program approach is not acceptable from the government's perspective, Kraft recommends that FSIS begin to adopt Good Manufacturing Practice (GMP) regulations, similar to those applicable to products regulated by FDA. Perhaps a regulation on environmental controls, including microbiological monitoring as a self-audit of performance, would be an appropriate first step. FDA has general GMP regulations for food manufacturers and a specific GMP regulation requiring internal audits for medical device manufacturers, 21 CFR 820.22; 43 FR 31508; July 21, 1978, which might serve as models for an FSIS environmental testing program.

Just as the success of an internal audit depends upon discovering and correcting deficiencies, a successful environmental monitoring program must uncover sources of *L. monocytogenes* in the processing environment.
Both are effective, only if the manufacturer is encouraged to find and address deficiencies. For that reason, we respectfully ask FSIS to review the preamble commentary accompanying the final medical device GMP regulations, 43 FR 31515-16, which explains why FDA decided to refrain from directing inspectors to examine records developed during the course of an internal audit, absent

extenuating circumstances. The currently applicable Compliance Policy Guide, 130.300, which directs investigators to check that a program is in place, but refrain from routine inspection of records, remains in effect "to encourage firms to conduct quality assurance program audits and inspections that are candid and meaningful." Kraft urges FSIS to consider the same approach to foster the effectiveness of internal audit tools designed to enhance *Listeria spp* control. In other words, except for investigative and similar extraordinary circumstances, environmental testing results should be treated as confidential and not routinely reviewed by FSIS inspectors; and, because environmental monitoring programs are necessarily complex, any dispute concerning the implementation and management of the monitoring program, the use, availability, and interpretation of test data, or the company's corrective action plan, should be resolved in consultation with the FSIS Technical Center.

SPECIFIC COMMENTS

Performance Standards

In the action plan, FSIS notes that the agency intends to publish a proposed rule to establish performance standards for ready to eat products. The agency's intent is unclear to Kraft, particularly with regard to *L. monocytogenes*. At present, we understand that FSIS has zero tolerance for *L. monocytogenes* in ready to eat foods. If our understanding is correct, the proposal would seem to be redundant or potentially in conflict with existing regulatory requirements. If FSIS is considering a tolerance above zero, which may well be appropriate as product formulas that do not support growth are developed and as we gain more understanding of the infective dose for at-risk individuals, it would be helpful for the agency to publish a proposal for comment as a next step.

Listeria Control Programs

From a scientific basis, confirmed over years of experience, Kraft knows that one of the most effective tools in managing *L. monocytogenes* is monitoring and controlling the processing environment. The goal of such a program is to aggressively look for *Listeria* spp within the manufacturing environment and implement effective corrective actions designed to eliminate it. This may involve additional testing, equipment modifications, and employee training. Importantly, due to the ubiquitous nature of the organism and the continuous opportunity for introduction into the environment, a positive result during environmental monitoring does not imply that foods are *L. monocytogenes* positive, nor does it necessarily presume a processing deficiency has occurred.

Environmental testing must remain flexible to address unique processes of each individual facility. Kraft -- and all manufacturers – must have experts design investigations and diagnostic testing protocols based on each individual situation. Neither the company nor the government could design an effective

program to resolve an incident in which *L. monocytogenes* is detected in the processing environment without a thorough understanding of the particular relevant facts. Therefore, Kraft opposes a "one size fits all" prescriptive program that inevitably will not deliver the protection needed for consumers.

Assuming that the particular details of the program are established appropriately for the individual establishment, Kraft offers the following example of an environmental monitoring program.

Such a plan would include the following components:

- Each line would be sampled weekly using a composite sponge sample. Each swab would be a composite of 4-10 locations. These locations should include but not be limited to direct food contact surfaces only. These samples should be analyzed for *Listeria* spp which is the best known indicator for the pathogen. All programs must be flexible to enable periodic adjustments as more information becomes available and technology improves. Therefore, FSIS should not mandate specific program details through the regulatory process.

- Negative results – in other words, the absence of the pathogen -- would require no action other than continued weekly sampling.

- A positive weekly composite would require that additional swabbing be conducted (for diagnostic purposes), that other investigative activities be performed, and that corrective action steps be taken and documented.

  Examples of possible investigative activities, which must be specified based on the particular situation at hand, would include:
  - Review cleaning records
  - Audit cleaning procedures
  - Conduct tear down inspections
  - Conduct pre-op inspections
  - Review environmental data
  - Review historical swab data
  - Review maintenance and downtime records

  Examples of possible corrective actions would include:
  - Intensified cleaning
  - Reinforce GMP training
  - Rewrite equipment cleaning protocol
  - Equipment redesign

- When successive positives are found, diagnostic testing would be initiated and would continue until the source of contamination is identified and corrected.

Shelf-Life Validation

Kraft has concerns about FSIS's plan to propose that establishments "validate the accuracy of handling/open dating information in their HACCP plans." Open dating is used to assure product quality, as explained in the Uniform Open Dating Regulation adopted by the National Conference on Weights and Measures, NIST Handbook 130, page 120, sections 1.1, 2.3. Open dating is not used to assure safety, nor would this be an appropriate use of a "best when sold or used by" dating system. Similarly, handling information is provided for the consumer's benefit to insure quality, not safety, particularly in ready to eat foods, which are subject to a zero tolerance policy. Shelf-life testing establishes an approximate date when the product quality begins to deteriorate and the manufacturer prefers that consumers no longer use the product, due to the significant possibility that they will be dissatisfied with the product quality and value. As long as product remains in channels of distribution, safety must be assured, regardless of product expiration date. Shelf life test protocols are not intended to and, indeed, cannot establish a definitive line between safe and unsafe products.

Furthermore, it is not clear what the Agency's expectations are with respect to a shelf-life date on RTE products. Given the current zero tolerance for *L. monocytogenes* in RTE products, validating shelf-life is not necessary. In addition, in our opinion, it is premature to issue a proposed rule on shelf-life validation before the completion of the ARS/FSIS Hot Dog Study, which is likely to provide relevant data within the next 7 months.

Secondary Barriers

Ingredients that reduce/eliminate the growth of *L. monocytogenes,* such as lactate, diacetate, and nitrite, serve only as a secondary microbial barrier; primary control is obtained through utilization of proper cooking and chilling procedures and by the effective implementation of prerequisite programs such as Good Manufacturing Practices, sanitation, environmental monitoring, and ingredient controls. The secondary barrier is not a critical control point by definition, because the existing critical control points assure that the product meets the zero tolerance requirement and that hazard, therefore, is not reasonably likely to occur. Inclusion of secondary barriers in the HACCP plan would be a disincentive to manufacturers and would discourage their use, due to the difficulty of analyzing complex food matrices for the microbiological inhibitor and the need to measure the inhibitor content in real time.

Finished Product Testing

As previously stated, *L. monocytogenes* control is most effectively managed using an aggressive environmental monitoring control program. Kraft firmly believes that resources should be focused in this area.

Testing finished product for pathogens has limited utility, even as a verification tool. Even with the most statistically sound and the most sensitive sampling method, it cannot be determined with certainty that the analyzed product is free of the target pathogen (i.e. the rate of error inherent in the best available current testing methodology may be as high as 1.5%). False positives unfairly penalize facilities that have an effective environmental monitoring program, have eradicated it from the manufacturing equipment, but nevertheless falsely tested positive. Regulatory action taken as a result of these false positives would cause unjustified deterioration of consumer confidence in the safety of the company's products, the general food supply, and the effectiveness of the government regulatory programs. In addition, false positives would result in the unnecessary annual destruction of millions of pounds and dollars worth of wholesome, safe product.

Industry Guidance

Kraft fully supports the development of industry guidance regarding appropriate intervention measures to reduce the risk *of L. monocytogenes*. We agree there is a need to continually educate processors as technology and control practices evolve. Manufacturers need to know what to look for in equipment design, how to test the environment, and the types of remedial actions that can be taken when indicators such as *Listeria* spp. are found. Kraft is working with a number of trade associations to develop training programs that focus on sanitation, environmental monitoring, handling of raw materials, and employee hygiene. We will continue to make these documents and training programs available to the industry. In addition, Kraft has been training our suppliers and co-manufacturers in these practices.

In-Depth Verification

Control of *L. monocytogenes* is an extremely complex process involving adequate thermal processing and environmental control. Kraft bases its *Listeria* spp. control program on the use of HACCP to verify the lethality of all thermal processes used in the manufacture of RTE products. Disciplined environmental control of *Listeria* spp. is effectively managed through prerequisite programs that support the HACCP program. FSIS must recognize during the in-depth verification review process the role that these programs -- GMP's, SSOP's, and environmental testing -- play in supporting the HACCP plan. These elements are not real-time critical control points that can be included in a HACCP plan.

Those FSIS employees that conduct the verification review will need extensive in-depth training in HACCP principles and environmental management of

pathogens. At Kraft, for example, we require internal auditors to have at minimum an undergraduate degree in microbiology or food science, and be trained extensively in the principles of HACCP. FSIS resources should be prioritized against those processors that lack appropriate resources to manage the risk of *L. monocytogenes.*

Finally, Kraft believes there is no value in mandating the in-depth review process since proper management of a HACCP system includes this process.

Inter-agency Risk Assessment

In light of our knowledge of consumer behavior, we are particularly concerned about how the results of the inter-agency risk assessment will be communicated to the public.

In December 1999, Kraft conducted both qualitative and quantitative research studies, which both showed that information on specific food products at risk for harboring *L. monocytogenes* has a negative impact on potential consumer behavior. In focus groups participants reported that categorizing foods as low, medium, or high risk for different populations would result in avoidance of certain foods, regardless of their individual health status. In addition, the quantitative testing showed about 50% of the consumers surveyed claimed that they would not buy products that had been identified as having a risk of containing *Listeria moncytogenes.*

Kraft strongly encourages FDA and FSIS to continue to work with communications experts such as the International Food Information Council, the medical community and others to develop and deliver effective messages to the public concerning the *L. monocytogenes* Risk Assessment.

Based on learnings from a qualitative study which we conducted in 1999, Kraft recommends that these messages on *L. monocytogenes:*

- be communicated in straight-forward, easy to understand, non-inflammatory language
- include information about pasteurization, when it applies, such as with pasteurized dairy products
- clarify "at risk" groups and what preventive measures are appropriate for "at risk" populations versus healthy adults
- provide information on appropriate food preparation and food handling procedures in and away from home

Public Messages to At-Risk Consumers

Kraft supports the development of appropriate public messages for susceptible populations. We encourage FSIS to continue to work with FDA and others to

determine appropriate messages and targeted programs to deliver them so they more effectively communicate actionable information for consumers.

In terms of labeling, we believe that storage and preparation instructions on food products provide adequate and useful information to consumers. However, we strongly oppose the use of warning statements, as they not only have the potential to be ineffective, but also misleading.

A study published in the journal of the *American Veterinary Medical Association* (Vol. 209, No.12, Dec. 15, 1996) showed that only 12% of the 2,465 consumer surveyed reported that safe food handling instructions on raw meat and poultry labels influenced their food handling behaviors. The author concludes that "when read, safe food handling instructions may improve food safety awareness of consumers, but only a fraction of adults have seen the label" and recommends that "other efforts should be explored to enhance awareness of safe food handling" (p.2056).

Finally, we believe that consumer messages intended to provide information to vulnerable populations should be carefully developed and programs for delivering those messages should be targeted not only to at-risk populations, but also to professionals who work and communicate with such groups of individuals (i.e., physicians, daycare providers, teachers, and health care workers). This will avoid unnecessary alarm among the general, healthy population.

Research

ARS, at the request of FSIS, has designed a study to examine prevalence and grow-out of *L. monocytogenes* in hot dogs provided by industry volunteer plants. Kraft fully supports these kinds of collaborative research initiatives as demonstrated by our participation in this study.

Kraft encourages FSIS to continue to conduct or fund research on approaches to control *L. monocytogenes*, including focus group testing of educational messages, measures to prevent growth of the organism in meat and poultry products, post-packaging pasteurization processes, and methodology to enumerate the organism in meat and poultry. There is still much to be learned about the ecology, pathogenesis, and control of *L. monocytogenes* and we urge FSIS to provide funding for additional research in this area.

New Intervention Strategies

Kraft is committed to developing effective programs to control contamination of products by *L. monocytogenes*, and we strongly believe that industry can work in partnership with FSIS and FDA to expand the portfolio of approved technologies and tools that can prevent/destroy food pathogens.

To achieve the shared objective of reducing illnesses from occurrence of *L. monocytogenes* in RTE foods, we would like to call on FSIS to work together with FDA to facilitate the approval process. The speedy approval of ingredients, technologies, and processes (e.g. irradiation of ready-to-eat products and packaging materials) is critical to the ultimate control *L. monocytogenes* and other pathogens in the food supply.

Equipment Certification

Kraft is very pleased that the Agricultural Marketing Service at USDA has published a proposal to develop an inspection and certification program for equipment used to process livestock and poultry products, using standards developed by NSF/3A. We look forward to reviewing the proposal in more detail.

SUMMARY AND CONCLUSIONS

Kraft advocates a program that combines stringent in plant environmental control, the use of environmental testing as a diagnostic tool, targeted education programs for at risk consumers, targeted regulatory monitoring programs, and a focus on higher risk foods. While we support an aggressive and stringent environmental control program, we believe it will be successful, only if the manufacturer has the ability to design and customize the program to address the unique processes within their facility, and if the results of environmental testing are maintained by the company as confidential and are available for FSIS review only under extraordinary circumstances.

In conclusion, Kraft is fully committed to food safety and we recognize the importance of controlling *L. monocytogenes* in RTE foods. The objective of reducing illnesses from the occurrence of *L. monocytogenes* is a challenging one, which will requires a considerable collaborative approach. As we well know, everyone has a responsibility for ensuring food safety from farm to table, including manufacturers, retailers, foodservice establishments, and consumers. We encourage the agency to look beyond the food processing industry – up and down the food chains -- to help minimize the risk of listeriosis.

Kraft offers these comments as part of our commitment to work cooperatively with government, consumers, and industry to continue to improve upon the safest food system in the world.

Respectfully submitted,

Jean Spence

Jean Spence
Vice President, Kraft Foods
Worldwide Quality & Scientific Relations