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June 7, 2000

FSIS Docket Clerk, DOCKET #00-016N
U.S. Department of Agriculture
Food Safety and Inspection Service, Room 102
Cotton Annex Building
300 12th Street, SW
Washington, DC 20250-3700

00-016N
00-016N-4
Leslie O. Sarasin

RE: Comments on the Revised Action Plan for Control of *Listeria monocytogenes* for the Prevention of Foodborne Listeriosis

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates the opportunity to comment on the Food Safety and Inspection Service's (FSIS) revised action plan for control of *Listeria monocytogenes* (hereafter referred to as *L. monocytogenes*) for the prevention of foodborne listeriosis. AFFI supports efforts by government in cooperation with industry and consumers to enhance food safety. Consistent with this shared objective, AFFI strongly recommends that actions taken by the agency to minimize the risk of foodborne listeriosis be appropriately prioritized based on scientific assessments of consumer risk. AFFI also believes that freezing is a powerful intervention strategy that helps to reduce the risk of listeriosis by preventing the growth of *L. monocytogenes* in foods.

AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 members are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally. AFFI represents almost all frozen further processed meat and poultry processors in the United States.

In response to the President's Directive issued on May 5, the agency has established a list of items that will be considered for rulemaking. The following are AFFI's recommendations on those issues of relevance to the frozen food industry.

A. Performance standards

The agency intends to publish a proposed rule to establish performance standards for shelf-stable and perishable ready-to-eat products that will address the need to reduce all pathogens. In addition, the agency is considering requiring that meat and poultry plants producing ready-to-eat products conduct environmental testing for *Listeria ssp.* in order to verify their Sanitation Standard Operating Procedures (SSOPs).

AFFI believes performance standards should be based on scientific data currently being used in the joint Food and Drug Administration (FDA)/FSIS *L. monocytogenes* risk assessment. The development of performance standards should be directed at products identified through the FDA/FSIS risk assessment as posing an increased risk for at-risk populations. Performance standards, if any are proposed, should take historical data into consideration. They should be developed for foods that support the growth of *L. monocytogenes*, have extended refrigerated shelf-life, have a high incidence of initial contamination and therefore present a greater risk to at-risk consumers. Frozen further processed meat and poultry products do not possess any of these characteristics. Therefore, increasing regulatory actions, such as mandating additional testing of these foods, is unjustified.

In general, AFFI members believe that mandating environmental testing of meat and poultry products is unnecessary. Voluntary environmental testing is widely practiced in industry and can be an effective tool to zero in on the root cause of an *L. monocytogenes* contamination problems and can assist in controlling the organism. The Institute believes there is adequate incentive for the industry to voluntarily establish environmental testing programs.

Where appropriate, voluntary environmental testing should be encouraged by the agency through incentive programs such as reduced finished product testing by FSIS for companies that conduct rigorous, science based environmental testing. Any testing program developed must remain flexible to fit the needs of each individual facility. Importantly, a positive result during environmental testing does not indicate that food products are contaminated with *L. monocytogenes*. The agency should assess the facility's response and corrective actions to a positive environmental test for *L. monocytogenes*, but should not punish the facility for engaging in preventive measures.

If the agency intends to mandate environmental testing for all ready-to-eat meat and poultry products, reduced end-product sampling programs conducted by FSIS may be of interest to some companies. However, if punitive actions were to result from positive *L. monocytogenes* environmental tests, participation in reduced sampling programs is likely to be minimal.

B. Validating handling instructions and/or open dating

Manufacturers should be encouraged, not mandated, to validate the lethality of cooking/handling instructions on foods. Liability for product safety and brand protection currently provides large incentives to manufacturers to ensure that cooking/handling instructions provide for destruction of pathogens.

For frozen meat and poultry further processed products, open dating is a voluntary program meant to be a measure of quality rather than a tool to ensure food safety. AFFI members believe that open dating is unnecessary and should not be required of frozen meat and poultry further processed products because they do not support the growth of *L. monocytogenes*. Additionally, consideration of any open dating regulations for meat and poultry that support the growth of *L. monocytogenes* should be delayed until the "Hot Dog Shelf Life Test" study is completed. This is a cooperative study between industry volunteers and FSIS to determine optimal shelf-life for hot dogs.

C. Finished product testing

AFFI recommends that end-product testing be voluntary. End-product testing does not verify whether a HACCP system is working for processed products because the low incidence of contamination renders the limited data practically meaningless. It also does not increase food safety in frozen products because growth cannot occur during frozen storage. Voluntary monitoring of the environment is more logical and is a better indicator to reduce the possibility of *L. monocytogenes* contamination.

Testing the entire contents of frozen "ready-to-eat" multi-ingredient products is not justified because freezing prevents the growth of *L. monocytogenes*. Importantly, it is the freezing that makes the product safe. AFFI members recommend that multi-component and single-component products currently characterized as "ready-to-eat" be reclassified as "not-ready-to-eat" and that they be exempt from testing especially if it is clear to consumers that these products need additional preparation before consumption, and cooking instructions have been validated.

The agency is considering testing multi-component products for both *L. monocytogenes* and *Salmonella*. Once again, AFFI submits that end-product testing does not enhance food safety. Testing an entire multi-component product for both *Salmonella* and *L. monocytogenes* is poor utilization of resources since the products associated with disease for the two organisms differ. Frozen products should be exempt from *L. monocytogenes* testing, as these products do not possess the risk factors identified by the risk assessment and have not been associated with listeriosis outbreaks. Additionally, testing an entire product may actually reduce the ability to detect *Salmonella* because it is normally associated with the meat ingredient of multi-component products.

D. In-depth verification reviews

AFFI believes verification of the effectiveness of HACCP systems on a regular basis is appropriate. However, it is our understanding that annual in-depth verification of the effectiveness of HACCP systems is already required. AFFI members agree it is important for facilities to reassess their HACCP plans when adding new products to the line or when acquiring new equipment. There is already ample incentive for facilities to verify and review their HACCP systems without being mandated to do so.

E. Interagency risk-assessment

Efforts made by both FDA and FSIS have resulted in a comprehensive draft risk assessment regarding *L. monocytogenes*. AFFI recommends that FSIS delay any policy decisions regarding *L. monocytogenes* until the risk assessment is finalized and can be utilized in a public discussion about policy changes. Further, AFFI recommends that the risk assessment be accompanied with a strong consumer education campaign developed cooperatively by industry and appropriate government agencies. Educational activities designed to address control of *L. monocytogenes* through home preparation should be targeted specifically to at-risk consumers. Failure to release a risk-assessment without educating consumers on the steps they can take to effectively control *L. monocytogenes* could result in decreased confidence in both the agency and the food industry domestically and internationally.

Concluding Remarks

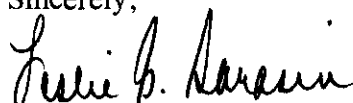
In conclusion, frozen foods do not support the growth of *L. monocytogenes* during normal use and storage conditions. As a result, they do not present an increased risk to consumers. The meat and poultry industries agree that frozen foods should not be the target of new or increased regulatory actions aimed at reducing the risk of listeriosis¹. AFFI believes that the agency's limited resources would be better used to educate consumers on how to handle products that are "truly" ready-to-eat. As FSIS is aware, freezing is a marvelous and appropriate intervention strategy to prevent the growth of *L. monocytogenes* and thus the potential of listeriosis illness. AFFI highly recommends that the agency promote the effectiveness of freezing in its educational campaign and inform the general public and specifically at-risk individuals that freezing meat and poultry products and leftovers is an effective strategy to prevent illness.

¹ 65 Federal Register. p. 30952.

AFFI Comments - *L. monocytogenes* Revised Action Plan
Docket #00-016N
June 7, 2000

AFFI appreciates the opportunity to share our views on the revised action plan for control of *L. monocytogenes* for the prevention of foodborne listeriosis. We look forward to the development of scientifically based policies that truly decrease the risk of contracting listeriosis through foodborne sources.

Sincerely,

A handwritten signature in black ink, appearing to read "Leslie G. Sarasin". The signature is written in a cursive, flowing style.

Leslie G. Sarasin, CAE
President and
Chief Executive Officer