

Department of Health and Human Services

Food and Drug Administration

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Risk assessment of the Public Health Impact from Foodborne *Listeria monocytogenes* in Smoked Finfish; and Evaluation of Food Code Provisions that address preventative controls for *Listeria Monocytogenes* in Retail and Foodservice Establishments. Request for Comments and for Scientific Data and Information.

The Association of Food and Drug Officials (AFDO) is a national organization which represents federal, state, and local government regulatory officials. By building consensus among food safety program managers at the state and local government level, AFDO is able to present united positions on national food safety matters which affect us all. These positions are further strengthened through our networking and information sharing with our associate members from industry and academia. It is through this organizational foundation and AFDO's active role in addressing public health concerns with *Listeria monocytogenes* that we are very pleased to offer these official comments.

AFDO's active role in this matter is well demonstrated by the following events which have occurred or are in process:

- 1) AFDO's model "Cured, Salted, and Smoked Fish Establishments Good Manufacturing Practices" (GMP) was updated in May 2004 and now includes the "Listeria Monocytogenes Control Manual" produced by the Smoked Seafood Working Group (SSWG) of the National Fisheries Institute (NFI) and the National Food Processors Association (NFPA). AFDO strongly supports the contents of this manual and within our model GMP, we have specifically recommended the following:

"All processed fish manufactures shall have developed and implemented a *Listeria* control plan to effectively control or minimize the potential for *Listeria* contamination of finished products. The *Listeria* control plan shall include the following elements:

- (a) Specific Good Manufacturing Practice (GMP) and Sanitation Controls,
- (b) Training Plant Personnel,
- (c) Environmental Monitoring in Exposed Finished Product Areas and/or Material and Finished Product Testing,
- (d) Finished Product Labeling,
- (e) Raw Material Controls"

While AFDO's model GMP are recommendations only, we do believe that any food establishment considered to be high risk for producing or providing ready-

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to-eat foods (RTE) for consumers must address *Listeria monocytogenes* through an action plan similar to the one developed by SSWG for smoked seafood products.

- 2) AFDO has formed a working group through a Cooperative Agreement with the United States Department of Agriculture; Food Safety and Inspection Services (USDA/FSIS) to survey, compile, and analyze state food sampling data for *Listeria monocytogenes*. Too often, state food sampling results are ignored by federal agencies and valuable information and insight is overlooked. In our view, this is unwise and not practical from a public health perspective.
- 3) AFDO has formed another working group through a Cooperative Agreement with USDA/FSIS to develop educational and training material for retail grocery store officials and government regulatory agencies relative to *Listeria monocytogenes* and measures to control its incidence in RTE food products. The materials will be produced through Penn State University and will include a video presentation, Power Point slide presentation, and training manual. AFDO will provide all developed materials to state food safety programs throughout the country.

These events and others demonstrate AFDO's strong desire to participate in any effort to establish strategies for effectively combating *Listeria monocytogenes*. Our specific comments to FDA in relation to conducting a risk assessment for *Listeria monocytogenes* in smoked finfish are as follows:

- 1) FDA should review and evaluate SSWG *Listeria monocytogenes* Control Manual and determine its effectiveness at manufacturing facilities that follow this plan. There is some evidence from New York State surveillance sampling that smoked fish products tested and found positive for *Listeria monocytogenes* at plants following this plan have been significantly reduced. (Ref. NYS Agriculture and Markets). AFDO believes that many of the control measures identified in the manual and applied at certain manufacturing facilities have been very effective in reducing the incidence of *Listeria monocytogenes* in finished smoked fish. These include the following control measures:
 - (a) Provide dedicated washing areas and systems for RTE product equipment and raw processing equipment.
 - (b) Use of high strength sanitizing solutions in foot baths.
 - (c) Use of listericidal lubricants and bactericidal drain rings.
 - (d) Innovative use of sanitizers that include rotating the types used and sanitizing at higher temperatures where permitted.
 - (e) Application of peracid-based sanitizers to floors, walls, drains, and coolers.
 - (f) Use of hot water/steam sanitation when equipment is difficult to clean.
 - (g) Use of anti-microbial dip or wash of raw or unprocessed product before it is cold smoked (i.e. 20-30 ppm chlorine.)

- 2) FDA should review and analyze state *Listeria monocytogenes* surveillance data for smoked fish with states who have conducted this testing. AFDO is willing to assist FDA with this important work if requested.
- 3) Added research is recommended for raw product process treatments for the following applications:
 - (a) Steam surface pasteurization.
 - (b) Washing raw fish with water containing chlorine or chlorine dioxide.
 - (c) Treating raw fish with calcium hydroxide.
 - (d) Use of Cecune (cetylopyridinium chloride-CPC) as an antimicrobial dip.
(Note: A petition to FDA is pending.)
 - (e) Use of an electro-chemical continuous in line system in brine tanks.
- 4) Whereas HACCP plans for cold smoked fish have no kill step for destruction of *Listeria monocytogenes*, FDA should require that sanitation standard operating procedures (SSOP's) are strictly followed and monitored and that specific *Listeria monocytogenes* preventative and control measures be identified in the SSOP's.
- 5) In some state surveillance data, evidence is provided that further processing smoked fish creates a higher hazard situation. Products such as smoked fish salad and cut/sliced smoked fish portions have been shown to have higher incidence of contamination with *Listeria monocytogenes*.
- 6) FDA should review and analyze scientific literature on finished product treatments to control *Listeria monocytogenes* and make recommendations to manufacturers relative to the following:
 - (a) Addition of nisin to cold smoke vacuum packaged fish.
 - (b) Effectiveness of competitive lactic acid bacteria flora in cold smoked fish.
 - (c) Additions of sodium lactate in cold smoked fish.
 - (d) Effectiveness of varying combinations of water phase salt, nitrites, and oxygen permeable packaging.

Although we are unaware of any outbreak of listeriosis being traced to smoked fish, it is clear that these products are high risk for contamination from this, often times fatal, pathogen. We are, therefore, very supportive of FDA's intention for conducting assessment.

Our specific comments to FDA in relation to Food Code provisions that address preventative controls for *Listeria monocytogenes* in retail and foodservice establishments are as follows:

- 1) FDA and AFDO have compiled excellent data from state programs relative to those agencies that have adopted specific Food Code versions. FDA should consider expanding this work with AFDO and survey state programs to determine if recognized *Listeria monocytogenes* intervention strategies from within the Food Code exist within the state regulation adopted. These may include

time/temperature requirements, training of the person in charge, date marking, time as a public health control, and HACCP requirement for specialized processing.

- 2) State food safety programs may require of retail and food service establishments additional control measures which are effective against *Listeria monocytogenes* that are not currently within the Food Code. FDA should determine on their own or in conjunction with AFDO, what these measures are. Examples of such measures may be, refrigeration of smoked fish at 38°F, specific cleaning frequency for equipment used for RTE foods, mandatory manager certification, and a broader application for the use of HACCP with retail processed products.
- 3) FDA should review any available food sampling data for *Listeria monocytogenes* conducted by state food safety agencies at retail and food service establishments. AFDO believes unique concerns and valuable insights from this data can be found by discussing this with state regulatory agencies.
- 4) Original versions of the Food Code and current versions of several state adopted codes include a time allowance for retailers to adapt to temperature storage requirements of 41°F. AFDO believes there is no longer a need for such allowance. Additionally, microbial growth rate data indicates there is a significant increase in growth of *Listeria monocytogenes* at 45°F as opposed to 41°F. Provisions for allowing 45°F storage should be eliminated from the Food Code and states which have such provisions should be encouraged to amend their regulations.
- 5) Most of the environmental testing and research conducted for *Listeria monocytogenes* in food establishments has been conducted at the manufacturing level. AFDO believes that FDA should fund or partner with some entity to study the incidence and prevalence of *Listeria monocytogenes* in grocery stores and restaurants. Currently, assumptions are made about “hot spots” and intervention strategies at retail based on what is known at food manufactures. Comprehensive studies of retail environments are sorely needed, in our view, as controls are generally establishment type and plant specific.
- 6) There currently exists great controversy concerning the need and value of environmental testing and record keeping at retail. Retailers express liability concerns while regulatory officials believe monitoring for *Listeria* spp. as an indicator of potential *Listeria monocytogenes* contamination is important. Some states have broadly written food processing regulations which allow them to require food stores that conduct food processing to conduct “microbiological testing”. This rule is generally used when surveillance or inspection samples of RTE food are tested and found positive for *Listeria monocytogenes*. AFDO believes that the FDA should demonstrate their leadership in this matter and offer an official opinion or position on this controversial matter.

- 7) An AFDO Workgroup is currently reviewing follow up protocols conducted by states when RTE foods have been tested and found positive for *Listeria monocytogenes*. The Workgroup will identify critical follow up steps taken such as seizure or embargo, operation closure, environmental testing, recall, and additional sampling. The Workgroup will recommend a uniform protocol to be considered by state and local regulatory agencies. AFDO will include the FDA in on this effort.

Because *Listeria monocytogenes* is so widespread in the environment, the task of preventing contamination is a difficult one. It is not possible to completely eliminate *Listeria monocytogenes* from the retail environment, but employing appropriate practices and control measures in retail and food service establishments can reduce the opportunities for this pathogen to cause contamination. It is critical that the Food Code contain such practices and control measures.



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