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Dockets Management Branch (HFA-305)

Docket No. **99N-1168**

Food and Drug Administration
5630 Fishers Lane, Rm. **1060**

Rockville MD **20852**

00-048N

00-048N-5

Roger L. Hancock

FSIS Docket Clerk

Docket No. **00-048N**

U.S. Department of Agriculture

Food Safety and Inspection Service, Rm. **102**

Cotton Annex

300 12th Street SW

Washington, DC **20250-3700**

Dear Sir or Madam:

Thank you for the opportunity to comment on the Relative Risk to Public Health from Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Draft Risk Assessment Document. The comments offered below are from the perspective of a national food retailer committed to selling safe food in clean stores. They do not offer an in-depth review of the statistics used to evaluate or extrapolate real data. Rather, these comments respond from an operational perspective to Main Topic 1, Assumptions, in the request for comments.

The Food and Drug Administration and the U.S. Department of Agriculture are to be commended for undertaking the important task of understanding the risk to public health from **L.** monocytogenes with the ultimate goal of risk reduction. The seriousness of listeriosis illness warrants thoughtful action to safeguard the public's health.

II. Hazard Identification

A full understanding of the epidemiological patterns of listeriosis is essential for designing interventions that effectively reduce its incidence.

The Draft Risk Assessment states, "Outbreaks of listeriosis are often associated with a **processing** or production failure whereas this has been less evident among sporadic cases." **The sampling** of food items from the refrigerators of sporadic case-patients does not distinguish between illness-causing food contamination and post-illness food contamination caused by the

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case-patient handling food. This food contamination, along with the data presented from the multi-state active surveillance project on sporadic listeriosis (20% of household patient-contacts had asymptomatic carriage), seems to suggest that person-to-person, and person-to-food post-illness contamination is not an infrequent event that may pass the bacteria without producing illness. Understanding this contamination with or without illness may shed significant light on the epidemiology of listeriosis and the risk associated with this type of contamination versus processing or production failures. In other words, Table II-3 is not definitively causative in the sporadic listeriosis cases, but may be resultant from the cases.

More research on the sources of the suspected causative foods for the sporadic cases is warranted. Linking sporadic cases to a source of contamination, not just a suspected food, is essential for developing intervention strategies that can be most effective.

III. Exposure Assessment

The breadth of the investigation into food sources, consumption patterns, and relative risk is extensive.

The inclusion of deli salads and fruits raises questions. The risk assessment reports no listeriosis cases arising from deli salad or fruit consumption as the confirmed causative agent. The data presented in Table III-7 for deli salads is admittedly speculative. The Exposure Assessment states, "No data [exists]; growth rate for deli meats was used as a surrogate for the food category [deli salads]." The differing pH levels, water activity, and preservative profiles suggest that such a comparison between Deli Meats and Deli Salads may be invalid.

Significantly, more research into actual contamination levels of deli salads needs to be done in order to support the development of action plans to effectively reduce any exposure to *L. monocytogenes* that may result from consumption of deli salads.

V. Risk Characterization

The impact of the assumption about *L. monocytogenes* growth in Deli Salads made in Section III, Exposure Assessment, carries forward to the Risk Characterization with seemingly unrealistic results.

Deli Salads, which are not directly tied to any known listeriosis cases or outbreaks reported in the Risk Assessment, are shown in Figure V-1 to have a higher predicted relative risk for causing listeriosis than Frankfurters, Soft Mold-Ripened and Blue-Veined Cheese, Pasteurized Fluid Milk, Dry/Semi-Dry Fermented Sausages, and Vegetables, all of which have been directly tied to listeriosis outbreaks.



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The influence that this Risk Characterization is likely to have on policy decisions regulating the food industry lacks the sound scientific backing needed to ensure effective measures to reduce listeriosis.

VI. Interpretation and Conclusions

In general, the Interpretation and Conclusions appropriately characterize the findings of the Risk Assessment as a good starting point for further research. However, since as stated, "...a substantial degree of variability and uncertainty exists around the models' predictions," great restraint must be used in drawing operational conclusions for new regulations from this Draft Risk Assessment. Even using the results as a "...means of comparing the relative risks among the different food categories and subpopulations," must be done with great caution to prevent overburdening an already highly regulated industry with further regulations that will not have the intended effect of reducing listeriosis.

Again, thank you for allowing Albertson's to comment on the Draft Risk Assessment. We look forward to continuing to work cooperatively with both the F.D.A. and the U.S.D.A. to protect the public's health through food safety.

Sincerely,

ALBERTSON'S, INC.

A handwritten signature in black ink, appearing to read "Roger L. Hancock", written over the typed name.

Roger L. Hancock
Corporate Director of Food Safety
and Sanitation

RLH/jcd

cc: Clement Stevens
Ertharin Cousin
Steve Hilton
Kathy Brady
Ken Rosenwinkel
Jill Hollingsworth, FMI