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Joan Claybrook, President

September 10, 2001

Dockets Management Branch (HFA-305)
Docket No. 99N-1168
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

00-048N
00-048N-16
Wenonah Hauter, Director

United States Department of Agriculture
FSIS Docket Room
Docket No. 00-0048N
Docket No. 97-013P
Room 102 Cotton Annex
300 12* Street, S.W.
Washington, DC 20250-3700

Dear Sir or Madam:

On behalf of Public Citizen, a consumer organization, I would like to make the following comments concerning the Draft Risk Assessment and Risk Management Action Plan and the proposed Performance Standards for the Production of Processed Meat and Poultry Products to control the spread of ***Listeria*** *monocytogenes* on ready-to-eat foods. Public Citizen represents some 150,000 members.

We find several glaring omissions from the proposed action plan and the proposed rule. First, there is no mandatory review of companies' Hazard Analysis and Critical Control Points (HAACP) plans by USDA and FDA inspectors to ensure that measures are being undertaken to control ***L.*** *monocytogenes.* Without such review, private industry may be ignoring potential sources for this food-borne pathogen in processing plants.

Second, there is no mandatory requirement for either USDA or FDA inspectors to report the outbreak of *L. monocytogenes* to their respective agencies. We have learned of a recent instance

in a Iowa plant that processed turkey deli meats in which the product tested positive for ***L. monocytogenes*** after it left the plant and placed in cold storage ready for shipment. Company officials along with a USDA compliance officer urged USDA inspectors not to report the outbreak of the pathogen in order to spare the company of any embarrassment. In light of the recent revelations concerning the **1998-1999** outbreak if ***listeriosis*** emanating from Sara Lee Corporation's Bil Mar plant, it would behoove plant workers and government regulatory officials to report truthfully and accurately all incidents associated with this deadly pathogen.'

Third, a high priority should be placed on identifying potential sources for ***L. monocytogenes*** for government inspectors and those potential sources should be incorporated into companies' Sanitation Standards Operating Procedures.

Fourth, we believe that the frequency of the testing in all food plants should be increased. Moreover, the timing of the testing should be staggered so that not all of the mandatory tests are conducted on one day.

Fifth, resources should be invested into developing technology that would provide for continuous testing of all product for ***L. monocytogenes*** and other food-borne pathogens.

Sixth, all product emanating from a food processing plant that tests positively for ***L. monocyogenes*** should be held and not released into commerce until the source of the pathogen has been identified and eliminated. Furthermore, when a positive result is registered, all product from that particular shift should be tested to ensure the safety of the food before it enters the food supply.

Seventh, prospectively, we would like to register our opposition to the section of the proposed rule on performance standards for certain ready-to eat products that would permit the use of irradiation to treat ready-to-eat products to control ***L. moncocytogenes.*** As you know, the Food and Drug Administration is currently reviewing comments on an industry petition that would permit irradiation of certain ready-to-eat products. Public Citizen has conducted extensive research on the issue of food irradiation, and we are concerned that the Food and Drug Administration has not followed its own protocols when testing irradiation for its safety.[2] We are also alarmed that when asked what ready-to-eat foods would be covered by the industry petition, officials at the FDA are not able to identify the scope of coverage.[3]

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[1] "Workers: Bil Mar Knew Meat was Bad," ***Detroit Free Press,*** **August 30,2001.**

[2] "A Broken Record: How FDA Legalized – and Continues to Legalize – Food Irradiation Without Testing It for Safety,'' Public Citizen, The Cancer Prevention Coalition, Global Resource Action Center for the Environment, October 2000.

[3] Docket Number 99F-5522, Food and Drug Administration.

We appreciate the opportunity to comment on this important public health issue. Should you have any comments regarding our positions on this matter, please feel free to contact me at (202) 454-5 150.

Sincerely,

Wenonah Hauter, Director
Critical Mass **Energy and Environment Program**