United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

JUN 6 2003

Ms. Ashley R. Radel
2008 South Avenue
Marion, Ohio 43302

Dear Ms. Radel:

This is in response to your letter to Dr. Garry L. McKee about irradiation of meat products. We apologize for the delay in our response.

The Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA) is the public health agency responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which require Federal inspection and regulation of meat, poultry, and processed egg products prepared for distribution in commerce for use as human food. The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) has jurisdiction over other foods, other than meat, poultry, and processed egg products, such as fruit.

FDA is responsible for approving the safety of food additives (including ionizing radiation). FSIS is responsible for approving their effective use (at the lowest level) in meat, poultry and egg products. For more information about irradiation, go to: *http://www.fsis.usda.gov*.

Your letter shows that you are knowledgeable about irradiation. FSIS views irradiation, when used in conjunction with hygienic slaughter and processing procedures, as one of several options for increasing the safety of meat and poultry. Many years of research and practical demonstration have established that irradiation will reduce microorganisms that cause foodborne illness in meat and poultry. As you noted, the safety of irradiated foods has been evaluated by FDA and by scientific and medical experts from many health-focused organizations, including the American Medical Association. All have concluded that the irradiation processes for the use just described is safe and effective.

You may be interested to know that new provisions written into the Farm Bill direct that USDA "shall not prohibit the use of any technology to improve food safety that has been approved by the Secretary of Agriculture or has been approved or is otherwise allowed by the Secretary of Health and Human Services" for use in various commodity purchase programs, such as the school lunch program. Other provisions in the Farm Bill direct the Secretary of HHS to conduct rulemaking on revising the current regulation governing the labeling of foods that have been treated by irradiation. Because such rulemaking will be the primary responsibility of FDA, we have forwarded a copy of your letter to that Agency for a response. If you would like to contact FDA directly, the mailing address is: FDA, HHS, Office of Consumer Affairs, HFE-88, 5600 Fishers Lane, Rockville, Maryland 20857.

99F-5522

C 86

You also may be interested to know that the National Food Safety & Toxicology Center at Michigan State University hosted the First World Congress on Food Irradiation. The meeting was held May 5-7, 2003 at McCormick Place, Chicago, Illinois. More information is available at *http://www.foodsafe.msu.edu*.

We hope this information is helpful. Thank you for writing.

Sincerely,

Philip S. Derfler
Deputy Administrator
Office of Policy and Program Development

cc: FDA, HHS
Office of Consumer Affairs
5600 Fishers Lane, HFE-88
Rockville, Maryland 20857

2008 South Avenue
Marion, OH 43302
17 November 2002

Dr. Garry L. McKee
Administrator
Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Dear Dr. McKee:

The United States Department of Agriculture (USDA) reported a nearly 50% increase in meat samples containing Escherichia coli 0157:H7 from 2001 to 2002 (1). Irradiation is the most logical and effective way to protect consumers from E. coli 0157:H7 in meat. Someone in your position has the influence to change the policy of food safety, and I propose that you enforce irradiation as a means for eliminating the E. coli 0157:H7 pathogen.

According to Centers for Disease Control E.coli 0157:H7 is responsible for 62,458 illnesses, 1843 hospitalizations and 52 deaths every year costing between $230 and $600 million in medical and productivity costs (5). The production cost of irradiating beef depends largely on the size of the plant. A plant that processes 50 million pounds of beef would have a higher net benefit than a plant producing 12 million pounds because the larger plant produces more and has a greater impact on the health of consumers (2). The plants not capable of irradiation inside their facilities would have to ship their meat to irradiation facilities. These plants would pay an average of 3 to 5 cents per pound. The plants that do have irradiation facilities would spend an average of 1 cent per pound to decontaminate their meat. The cost of building a cobalt-60 irradiation plant is $3 to $5 million dollars (3). Raising the price of beef 1 to 5 cents per pound could pay for the cost of the facility. The USDA estimates that for every $1 spent there is $2 worth of savings in reduced spoilage and illness (2). Consumers will be willing to pay for the cost after learning the benefits of the irradiation process.

Some people are mislead to believe that irradiation will cause the food to be radioactive, and unfit for human consumption. The packages are required to have labels with the radura symbol signifying the meat has been in contact with radiation. Along with that symbol should be a statement claiming why the food has been irradiated and that it has been proven safe and free from pathogens causing food borne illness, how to store food to maintain quality, the proper handling procedures such as cooking temperatures and what is required from the consumer to further ensure safety for consumption.

Some feel that vitamin loss is too significant, that vitamins such as A, C, E, K and B that are destroyed during irradiation are also destroyed when the meat is cooked. Research by the Food and Drug Administration proves that this process can be reduced by lowering the temperature or the absence of oxygen during the process (4). The irradiated food is

often misconstrued as radioactive, but the Food and Drug Administration (FDA) has set maximum levels of radiation allowed for foods, and the gamma rays allowed are too low to cause the beef to become radioactive (2). The American Medical Association, Centers for Disease Control, and the World Health Organization endorse the use of irradiation to eliminate food borne diseases claiming that it improved the quality of meat absent from pathogens such as E. coli 0157:H7 (2). The most important aspect is that irradiated meat is safer than non-irradiated because the latter has pathogens that are potentially deadly. Irradiation is not a catch all for meat. Proper handling in the meat packing plants and in homes is essential for safety.

The food is often irradiated in its final package to prevent further recontamination, which creates a problem with the meat packing plants lowering their standards. The USDA determined that 78% of meat contained microbes that are spread through feces (6). Irradiation is not meant to decontaminate the meat from improper handling, it is to ensure that pathogens are destroyed. The Hazard Analysis Critical Control Point (HACCP) program is designed for plants to create and implement policies to prevent the mishandling and carelessness that results in further contamination. Inspectors are a vital part in ensuring the plants are following the HACCP guidelines.

Safety of workers in these radiation facilities is extremely important. They must be qualified and meet the requirements set by the Food and Drug Administration. The FDA requires that the facilities be designed for fail-safe measures, have extensive and well documented safety procedures and the workers are extensively trained (6). The U.S. Department of Transportation is responsible for regulating the transportation of radioactive materials (6).

The sooner this policy could be implemented the greater the benefits to the consumers. Irradiation would save thousands of lives and billions of dollars. There are 170 facilities worldwide who use irradiation. Most are for sterilization of medical and pharmaceutical products, and I believe that the number of food irradiation plants should increase for the safety of the consumer. The human benefits are enough to suggest that irradiation should become a routine part of the food process.

Sincerely,

Ashley R. Radel