



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JUN 06 2011

Betsy Booren, Ph.D.
Director of Scientific Affairs
American Meat Institute
1150 Connecticut Ave
Washington DC 20036

Dear Dr. Booren:

This letter is in response to your July 8, 2005 submission, *Citizens Petition to Recognize the Use of E-beam on Carcasses as a Processing Aid*. In your petition you requested that the Food Safety and Inspection Service (FSIS) officially recognize low dose, low penetration electron beam (e-beam) irradiation applied to the surface of chilled beef carcasses as a processing aid and, thus, such beef would be exempt from labeling. After reviewing the available information associated with this request (refer to attachment 1), FSIS believes that beef carcass geometry may lead to an uneven absorbed dose and is pertinent to the low dose aspect of the AMI petition, even though the petition did not provide a definition or criteria to use to define low dose or low penetration. In addition, because absorbed dose is accumulated upon each exposure of treated beef, such treated beef would need to be controlled in a manner to ensure that the total absorbed dose does not exceed the maximum approved absorbed dose. The petition did not address the control of potential multiple application of treatment. Consequently, FSIS has determined that the petition lacks sufficient detail to warrant investment in development of a rulemaking at this time. FSIS is denying the petition without prejudice. AMI may submit a revised petition for consideration addressing the issues discussed in greater detail in the attachment. Meanwhile, establishments can use the irradiation treatment on chilled beef carcasses as long as the product meets the requirements of 9 CFR 424.21 for total absorbed dose and 9 CFR 424.22 (c)(4) for labeling.

If you have any question, please contact Dr. William K. Shaw, Jr., Director, Risk, Innovations, and Management Division at 301-504-0852.

Sincerely,

Daniel L. Engeljohn, Ph.D.
Assistant Administrator
Office of Policy and Program Development

Attachment

Attachment 1: FSIS Response to the *Citizens Petition to Recognize the Use of E-beam on Carcasses as a Processing Aid*

FSIS tentatively concluded after initially reviewing the petition that there was merit to consider low dose, low penetration e-beam irradiation on the surface of chilled beef carcasses as a processing aid. Accordingly, on September 18, 2008, FSIS held a public meeting to review the information contained in the petition to provide an opportunity for the public to comment on the proposed use of e-beam irradiation as a processing aid under the conditions of use identified in the petition.

FSIS has reviewed the public comments and the additional scientific information AMI submitted in support of their petition that centered on a study with a maximum absorbed dose of 1 kGy. Dr. Alejandro Castillo of Texas A&M University found in the study, entitled *Directionality of E-Beam in Carcass and Produce* presented at the 96th Annual Meeting of International Association of Food Protection in Dallas, TX on July 13, 2009 that due to the unidirectionality of e-beams, the target's geometry affects the dose distribution. He found that conventional e-beam application did not deliver a relatively even dose of energy across irregular surfaces and beef carcasses would be considered an irregular surface. Consequently, it became evident that current technology could not be applied in a manner to limit the absorbed dose to treating the surfaces of beef carcasses at an absorbed dose of 1 kGy level without also approaching the maximum allowed absorbed dose level in other parts of the carcass due, in part, to the irregular shape of a carcass.

A second issue concerns low penetration and potential re-irradiation of product during further processing. Specifically, the petition characterizes the treatment as a surface treatment similar to other antimicrobial interventions used as processing aids. However, any irradiated beef, whether trimmed off the surface and incorporated into mixtures of irradiated and non-irradiated beef, would still need to be controlled in a manner to ensure that none of the resulting product is re-irradiated to exceed the maximum total absorbed dose allowed. This requirement is not similar to other antimicrobial treatments used as processing aids. At this time, the Agency does not see how a further processor could know whether the originating carcass or primal was treated with low penetration e-beam irradiation without controls in place such as labeling.

These issues were not discussed in the petition and FSIS has met with AMI and requested these issues be addressed. On August 6, 2009, in a letter to Dr. Engeljohn, AMI claimed that the beef carcass' geometry was not pertinent to the AMI Petition without fully supporting their position and did not discuss the potential product re-irradiation issue.

In summary, FSIS has determined that the petition lacks sufficient detail to warrant investment in development of a rulemaking at this time. FSIS is therefore denying

the petition without prejudice. AMI may submit a revised petition for consideration addressing the issues discussed in this letter. Meanwhile, establishments can use low dose, low penetration electron beam applied to the surface of chilled beef carcasses as long as the product meets the requirements of 9 CFR 424.21 for total absorbed dose and 9 CFR 424.22 (c)(4) for labeling.