Food Safety and Inspection Service (FSIS)

Low-Penetration and Low-Dose E-beam Irradiation as a Processing Aid
Public Meeting
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The Food Safety and Inspection Service (FSIS) is announcing that it has received a petition from the American Meat Institute (AMI) to recognize the use of low penetration and low dose electron beam irradiation on the surface of chilled beef carcasses as a processing aid.

One form of radiant energy used commercially is electron beam (e-beam). Energy from accelerated electrons is absorbed as they enter the surface of the product being irradiated. The electrons cause chemical bond breakage in the microorganisms, immediately, in addition to damaging their deoxyribonucleic acid (DNA)

- In 1999, FSIS amended its regulations (64 FR 72168, December 23, 1999) to permit the use of ionizing radiation for treating refrigerated or frozen, uncooked meat, meat by products, and certain other meat food products to reduce levels of foodborne pathogens and to extend shelf-life.
- The FSIS requires labeling of meat and meat food products that have been irradiated.
- Under FDA's regulations, processing aids include substances that are added to a food for their technical or functional effect during processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food (21 CFR §101.100 (a)(3)(ii)(*c*)).
- FDA's regulations provide that processing aids are not required to be included on product labels.
- On July 8, 2005, AMI submitted a citizen's petition to FSIS requesting that the Agency officially recognize low dose, low penetration e-beam irradiation applied to the surface of chilled beef carcasses as a processing aid.
- The petition requested that information concerning irradiation treatment not be required on the label of any products derived from the carcass.

The petition argues that low dose (≤ 1.0 kGy surface dose), low penetration (20mm) e-beam irradiation is a processing aid because the electron beam has a functional effect of reducing pathogens on the carcass surface, but that once the energy from the electrons is absorbed, there were no further functional effects from the irradiation.

According to the petition, low dose, low penetration e-beam application results in only a small portion of the carcass receiving the e-beam irradiation exposure.

- The petition presents evidence that the use of e-beam irradiation is effective in reducing levels of *Escherichia coli* O157:H7 on the carcass;
- has no effect on organoleptic properties or appearance of the carcass;
- has no lasting effect on shelf life of the carcass or of product derived from the carcass;
- and produces no significant loss of either macro- or micro-nutrients in the carcass or the product derived from the carcass.

***E. coli* O157:H7**

- In an Arthur et al 2004 study, *E. coli* O157:H7 was found on 76% of beef cattle animal hides.
- In a McEvoy et al 2003 study, results showed that *E. coli* O157:H7 can be transferred to beef carcasses during hide removal.
- There is a high probability that irradiation of beef carcasses could eliminate *E. coli* O157:H7 from the beef carcasses.

The Process is Effective at Reducing Levels of E. coli O157:H7

The USDA Agricultural Research Service's Meat Animal Research Center (MARC) conducted a study on the effectiveness of low-dose, low penetration e-beam irradiation in reducing levels of E. coli O157:H7 on chilled beef carcass surface cuts.

- Forty cutaneous trunci pieces were inoculated with *E. coli* O157:H7
- Twenty with a high concentration of 6 log cfu/cm2 (high inoculation) and
- Twenty with a low concentration of 3 log cfu/cm2 (low inoculation)
- One half of the high inoculated and low inoculated samples were treated with surface dosage of 1 kGy with approximately 15 mm of penetration.
- The remaining samples were not treated.
- Results for direct cell count plating show that the *E. coli* O157:H7 contamination of the untreated samples remained around the high inoculation level (7.2 logs after attachment, 6.6 logs at 48 hours and 5.9 logs at 120 hours)
- *E. coli* O157:H7 was undetectable after 48 hours in irradiated samples that had been inoculated at the high level and was present at approximately 0.1 log after 120 hours.
- Results for direct cell count plating show that while the *E. coli* O157:H7 contamination of the untreated samples remained around the low inoculation level (3.9 logs after attachment, 2.9 logs after 48 hours, and 2.6 logs after 120 hours)
- For the low inoculation level, the irradiation treated samples were undetectable for *E. coli* O157:H7 after 48 and 120 hours.
- The results of the Most Probable Number (MPN) analysis were similar to that from direct plating
- There was no low-inoculation sample at 48 hours and only one low-inoculation sample at 120 hours that had a MPN value above the limit of detection (minimum level of detection was 0.036 CFU/cm2)
- All of the high-inoculation samples were above the limit of detection

The Process does not have any Effect on Quality or Appearance

- The MARC's study also addressed effects of low dose, low penetration e-beam process on organoleptic properties of treated product.
- In MARC's assessment of organoleptic impact, the flank steak was used as the model muscle.

None of the flank steak sensory attributes (aroma intensity, off-aroma, tenderness, juiciness, flavor intensity, and off-flavor) were affected by any penetration treatment (10%-75% penetration).

- Three Hunter Color measurements (lightness, redness, and yellowness) were made in the MARC study, and all showed some treatment effects.
- the effects on lightness and yellowness were not linear with dose, and thus the investigators did not consider them to be meaningful treatment-related differences.

The effects of treatment on redness values were linear. However, the researchers concluded that the magnitude of the effect was slight and would likely have no impact on consumer acceptance.

The Process does not have an Effect on Shelf-Life

A study of the effects of low dose, low-penetration e-beam surface exposure on the shelf life of beef was performed by Silliker Inc.

- Six beef plates were designated "air-exposed," and three of these six were left untrimmed.
- Six beef plates were designated "vac-pac," and all were trimmed.
- Six of these twelve were treated with low level (1 kGy), low penetration (15 mm) surface e-beam irradiation.
- The other six were left untreated as controls.
- After the six beef plates were irradiated, the irradiated and control plates were randomly subdivided into four equal segments.
- Each segment was allocated into time slots of 1, 3, 6, and 9 days for air exposed, and 1, 10, 20 and 30 days for vac-pac.
- Microbiological tests were performed at each measurement time:
- Total aerobic plate count (APC) (35°C with aerobic atmosphere),
- Hetero- and homo-lactic acid bacteria (LAB) (30°C with micro-aerobic atmosphere),
- Total coliforms (35°C with aerobic atmosphere), and Biotype I *E. coli* (35-45°C with aerobic atmosphere).
- To provide a measure of oxidative rancidity, thiobarbituric acid (TBA) was analyzed throughout shelf life.
- For APC, LAB, and total coliform counts of air-exposed beef after nine days, the irradiated samples were within 1.5 logs of the non-irradiated samples.
- For APC and LAB counts of vacuum packed beef after thirty days, the irradiated samples were within 1 log of the non-irradiated samples, while the total coliform counts were equivalent.
- The vacuum packed beef TBA values ranged from limited, tolerably oxidized to somewhat oxidized over 30 days of shelf life.
- The air exposed beef TBA values ranged from limited, tolerably oxidized at 2 days of shelf life to oxidized at 9 days of shelf life.
- All samples were below the range of rancidity.

- Based on the results of this study, the authors believe that the initial antimicrobial effects of the treatment appear to have been minimal, and over the course of shelf life, the APC and LAB counts on the surface e-beam treated product increased to the point that quantitative levels nearly approximated the non-treated controls at the end of the storage period.
- In addition, one of the principal measurements of shelf life and product spoilage—rancidity--as measured by TBA indicated that the treated samples would turn rancid slightly before the non-treated controls.
- These data appear to demonstrate that the e-beam surface treatment of beef plates does not have a lasting effect on the product shelf-life.

The Process does not produce significant loses of Nutrients

A literature review and analysis on the effects of low dose, low-penetration e-beam irradiation on the levels of micro and macro nutrients was conducted by Dr. Donald W. Thayer, a retired USDA – ARS researcher

- Concerning macro-nutrients, Dr. Thayer found that there were no significant differences in the peroxide and iodine values of lipids following irradiation up to 10 kGy of the m. longissimus dorsi of beef.
- Also, there were no significant changes following irradiation in the malonaldehyde concentration in beef m. longissimus dorsi.
- Concerning micro-nutrients, Dr. Thayer found the water soluble vitamins in beef (niacin, vitamin B12, chorine, instill, and folacin) were "unaltered."
- One water soluble and one fat soluble vitamin (thiamin and tocopherol) would likely be decreased.
- For these two vitamins, Dr. Thayer estimated, worse case, that the maximum net decrease in the U.S. diet would be only 0.021% for thiamin and 0.014% for tocopherol.
- Dr. Thayer concluded that "beef carcass surface, low dosage (1.0 kGy) electron beam irradiation will not produce a significant loss of either micro- or macro-nutrients from the U.S. diet."

FDA

- FSIS has consulted with FDA about this issue, and FDA has advised FSIS that, tentatively, it would not object to treating low dose, low penetration e-beam irradiation on the surface of chilled beef carcasses as a processing aid.
- FDA is still considering this issue and will likely consult further with FSIS.

FSIS

FSIS has tentatively concluded that there is merit to consider low dose (≤1.0 kGy) and low penetration (20 mm) e-beam irradiation on the surface of chilled beef carcasses as a processing aid.

- Data submitted showed that low dose, low penetration surface e-beam irradiation will produce a significant surface reduction of *E. coli* O157:H7 on chilled beef carcasses.
- The e-beam treatment does not appear to have a lasting antimicrobial effect that would extend the shelf-life of the products, and it appears that there is no significant difference in color, odor, or taste between treated and untreated products.

- Relevant studies appear to support the assertion that the low dose, low penetration e-beam irradiation treatment would not produce any significant changes in the macro and micro nutrient content of the treated products.
- Further, the entire beef carcass is not irradiated, only the surface of the carcass.

Issues to be discussed

Is there any additional evidence to support or contradict the evidence presented in the AMI petition on the specific application of a low penetration of 20mm and low surface dosage of ≤ 1.0 kGy electron beam irradiation on the surfaces of chilled beef carcasses as a processing aid?

Is there any evidence indicating that FSIS should consider the cumulative effects of the absorbed dose delivered in accordance with the AMI petition and any subsequent absorbed dose, such as a result of further irradiation of ground beef?

Should FSIS consider requiring irradiation process controls if irradiation is considered a processing aid? If so, what would they be and what impact would they have on the low dose irradiation of chilled carcasses?

Are there factors that FSIS has not considered? If so, what are they and what impact would they have?