

Next Steps for Food Irradiation: Advancing Technology in a Highly Regulated Environment

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Grocery Manufacturers Association

An Advocacy, Value Chain and Scientific Powerhouse for
the Food, Beverage, and Consumer Products Industry



GMA Plays Many Roles

- Develops and promotes scientific, risk-based food safety practices and policies for members.
- Provide food safety technical assistance to members.
- Conducts food safety research.
- Promotes rational and effective legislative and regulatory solutions when needed.
- Shares expertise in international standard setting forums.
- Communicates food safety messages to policymakers, the media and consumers.



Irradiation Facilities are Increasing Worldwide

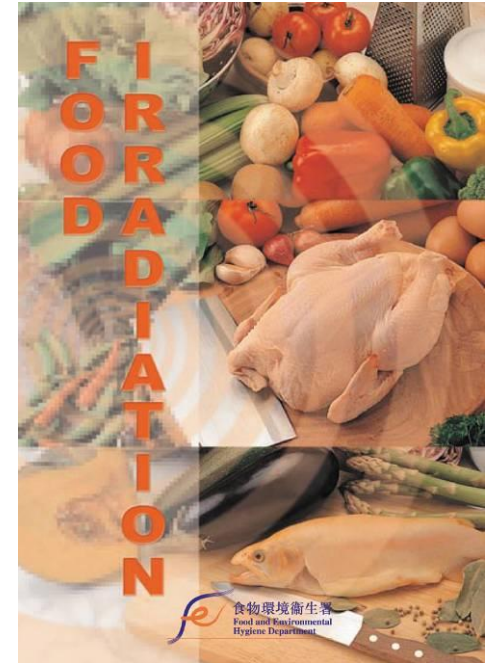


- Food irradiation is growing commercially.
- Many countries currently have irradiation facilities, including the U.S., Brazil, etc.
- Many additional countries have proposed, planned or recently renovated commercial food irradiation facilities.
 - Australia (1), China (3-7), India (3), Indonesia (1), Korea (1), Malaysia (1), Pakistan (5), Philippines (1), Thailand (1), Vietnam (2)



Brief History

- Discovered late 1800's – ionizing radiation preserves food quality, increases shelf-life & can be bactericidal.
- Late 40's interest by US government – extensive animal feeding studies.
- **1958 classified in US as a food additive, labeling required.**
- 1960's to date: 12+ approvals, 3 pending.
- 1980 Joint FAO/IAEA/WHO – up to 10kGy no toxicology, nutrition or food safety issues.



Brief History (continued)

- 1990's 40 countries have approvals, 28 use technology.
- 1999 Joint FAO/IAEA/WHO – any dose safe, no upper limit.
- 2000 GAO – benefits outweigh risk.
- 2000 Food Irradiation Coalition files R-T-E petition.
- 2004 FDA proposes rule for labeling based on “material change” criteria.
- 2010 GAO – FDA needs to better manage petitions (documents & timelines).



Regulatory Approval – Slow & Limited

- Petition was filed in Jan. 2000
- Very Broad Scope
- Partial Response
- Packaging
- Furan

**Food Additive Petition 9M4697
January 2000**

**USE OF IONIZING
RADIATION ON
CERTAIN
REFRIGERATED,
FROZEN OR DRIED
MEAT, POULTRY,
FRUIT OR VEGETABLE
PRODUCTS**

Food Irradiation Coalition

Recent Approvals

- Iceberg Lettuce & Spinach Approved by FDA in August 26, 2008

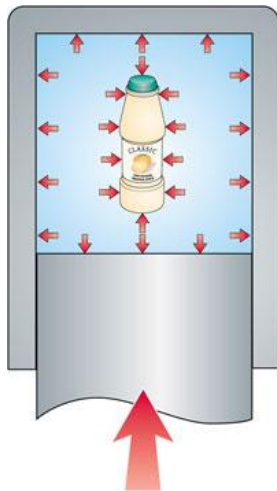


FAP 9M4697

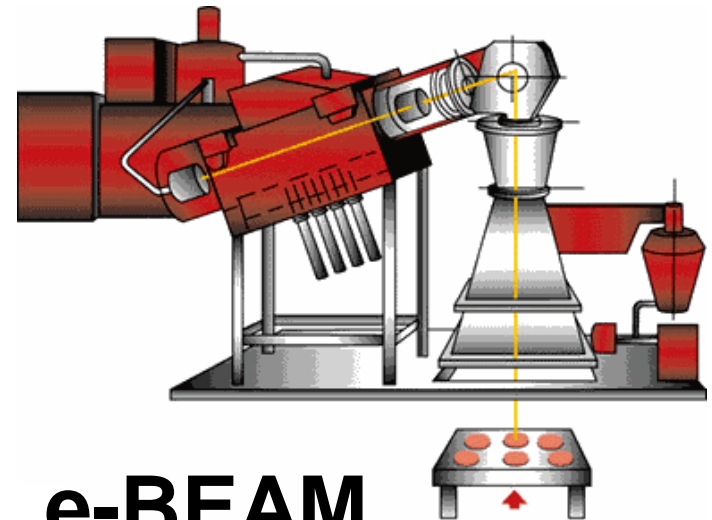


Where We Are Today...

- Recent Approvals for irradiation have been granted by FDA in the Food Safety arena and by USDA/APHIS for Phytosanitary purposes.
- Industry is actively looking at Food Safety needs and the application of other new technologies to enhance Food Safety.



HPP



e-BEAM

Where we would like to be in the future...

- Pending Approvals:
 - GMA has a petition in to FDA for approval of irradiation for RTE meats such as hot dogs, lunch meats, bologna, etc.
 - American Meat Institute has submitted a petition to the USDA FSIS for carcass irradiation as a “processing aid”.



Current Labeling & Radura

Retail “Treated With Radiation” or “Treated By Irradiation” and Radura

Ingredients: FDA Products – No Labeling;
USDA Products– Major Ingredients

Food Service: On Case to Establishment



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Consumer Acceptance – Still a Work in Progress

- '70s & '80s Hypothetical “willingness to buy” type studies – “if it were available”- test market studies.
- '80s & '90s Studies show food safety benefits seen with increased education – brochures developed.
- '00 & '01 Pathogens in produce and “Anthrax in mail” showed potential benefits of technology – consumer’s don’t connect the dots.
- Today’s consumer - without education, still thinks label means product is radioactive.
- *One solution – adopt FDA’s proposed labeling rule based on “material change” criteria.*

Voluntary Labeling

- Label must be truthful and non-misleading in all respects.
- Most value-added products would be labeled (a higher price needs to be justified).
- Label would describe benefits of treatment.
- **Use of terms is critical to acceptance**
 - Why? e.g. Treated for Food Safety
 - How? e.g. Cold Pasteurized; Ionized; Radiant Energy Treated
 - Education e.g. Ionizing Energy Kills Harmful Bacteria

Solutions Going Forward

Support the proposed FDA rule on labeling based on “material change”

- Mandatory Labeling → Voluntary Labeling

Support a change in the regulatory status of irradiation

- Food Additive → File a Scheduled Process



Regulatory Status Change

Draft Bill by Kit Bond (Sen. Missouri)

- *To amend the FFDC Act to remove radiation of food from the food additive classification.*

HHS would then:

- Establish rules prescribing the permissible use of sources of radiation.
- Amend the regulations and guidelines relating to HACCP to include irradiation as a critical control point.



Developing a Scheduled Process

- Review plans, drawings and monitoring practices for systems.
- Review the control systems and safety systems to determine CCP's and limits.
- Conduct microbial challenge studies to validate the process.
- Document dose mapping and establish max/min.
- Confirm use of approved packaging materials.
- **File process (paper or electronically) with appropriate agency (FDA or USDA).**
- Maintain records for each lot/batch of treated product.



Summary

- Technology works as a prevention strategy – basically a kill step without heat.
- Food irradiation is proven as a safe intervention step.
- The classification as a food additive has been an unnecessary burden for industry.
- The requirement for labeling has been a barrier to consumer acceptance.

Summary

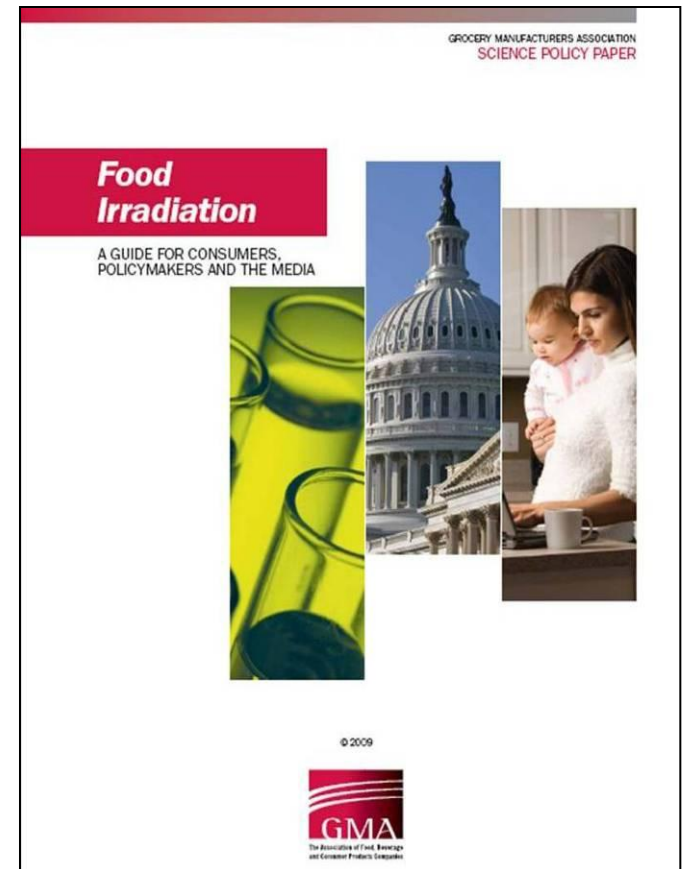
GMA supports:

- 1) FDA proceeding with a final rule on labeling based on a material change criteria.
- 2) Reclassifying food irradiation as a scheduled process and part of a HACCP plan.



GMA Science Policy Paper

Visit www.gmaonline.org to download an 18 page white paper on food irradiation.



Questions ?



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