

# Food Irradiation

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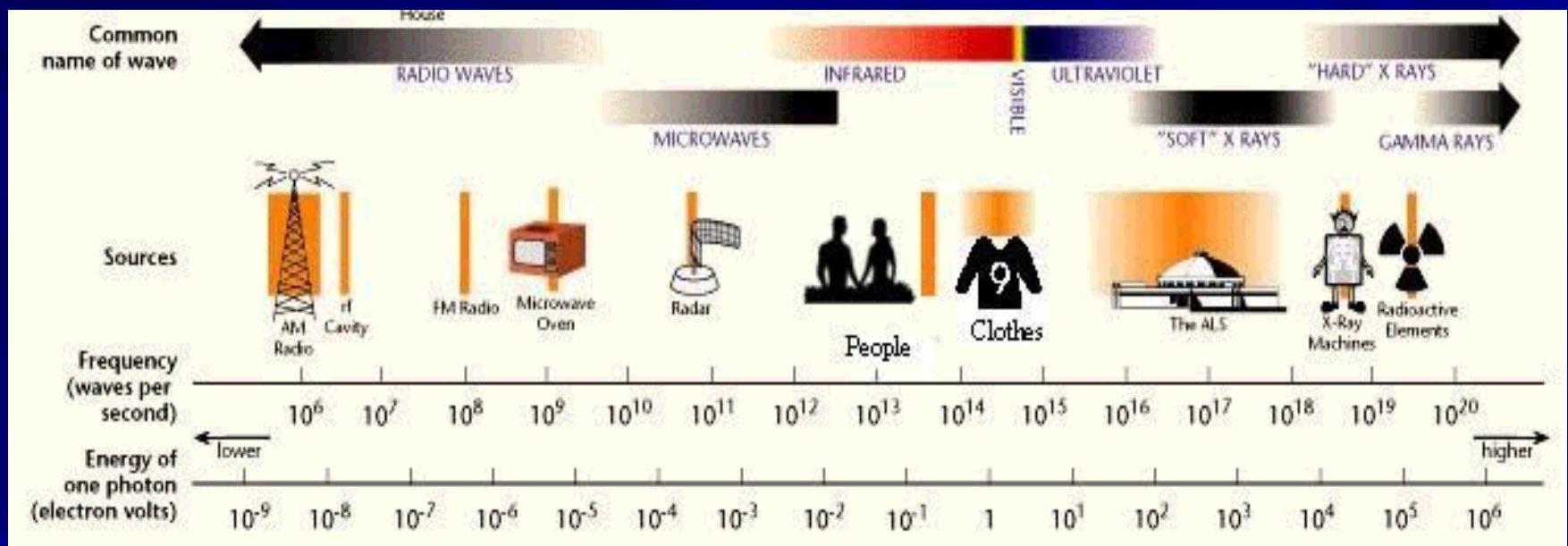
Division of Biotech and GRAS Notice Review

Office of Food Additive Safety

Center for Food Safety and Applied Nutrition

February 10, 2006

# Radiation Spectrum



# History of Food Irradiation

- **1905** Scientists receive patents.
- **1921** A U.S. Patent is granted for a process to kill *Trichinella spiralis*.
- **1943** Scientists show that x-rays can be used to preserve ground beef.
- **1950's** Beginning of era of food irradiation.
- **1953** Formation of the U.S. National Food Irradiation Program.
- **1955-1965** Army Medical Department program.
- **1958** Congress defines a source of radiation as a food additive.
- **1976** Food irradiation should be classified as a process.
- **1980** Foods irradiated up to 10 kGy considered to be safe and wholesome.
- **1997** Foods irradiated at any dose should be considered as safe and as wholesome as foods treated by any other conventional process.
- **2001** Irradiation is used to eliminate possible traces of Anthrax.

# Irradiation Facility

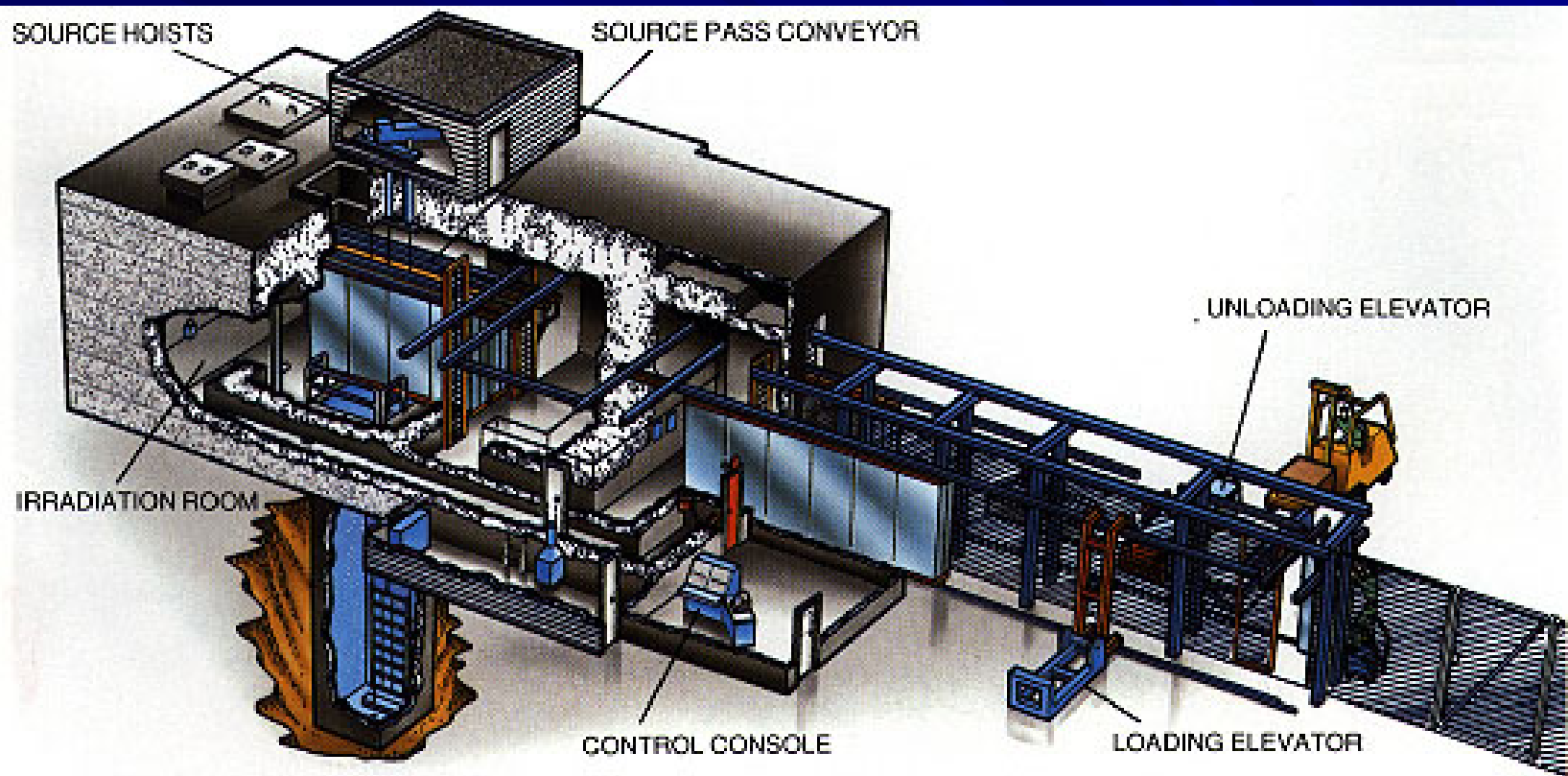


Figure 1: JS-8900 Unit Carrier Irradiator

# Federal Food, Drug, and Cosmetic Act

## ■ Sec. 201(s): Food Additive Definition

- Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; including any source of radiation intended for any such use)\*\*\*

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# Federal Food, Drug and Cosmetic Act

- Food additives are deemed unsafe until FDA writes a regulation
- Regulations stipulate an *identity*,  
*specifications* and *conditions of safe use*
- Regulations do not provide specific product approvals



# Sources of Radiation

- Cobalt 60
- Cesium 137
- Electron Accelerators Operated at  
10 MeV or Less
- X-ray Generators Operated at  
7.5 MeV or Less

# Why Irradiate?

- Low Dose (<1 kGy)
  - Control insects
  - Inhibit maturation
  - Inhibit sprouting
- Medium Dose (1-10 kGy)
  - Extend shelf life
  - Reduce microorganism level
- High Dose (> 30 kGy)
  - Sterilize - analogous to canning
  - Decontamination of certain food additives, e.g., spices

# Safety Considerations

- Radiological Safety
- Chemical Change and Potential Toxicity
- Nutritional Adequacy
- Potential Microbiological Hazard

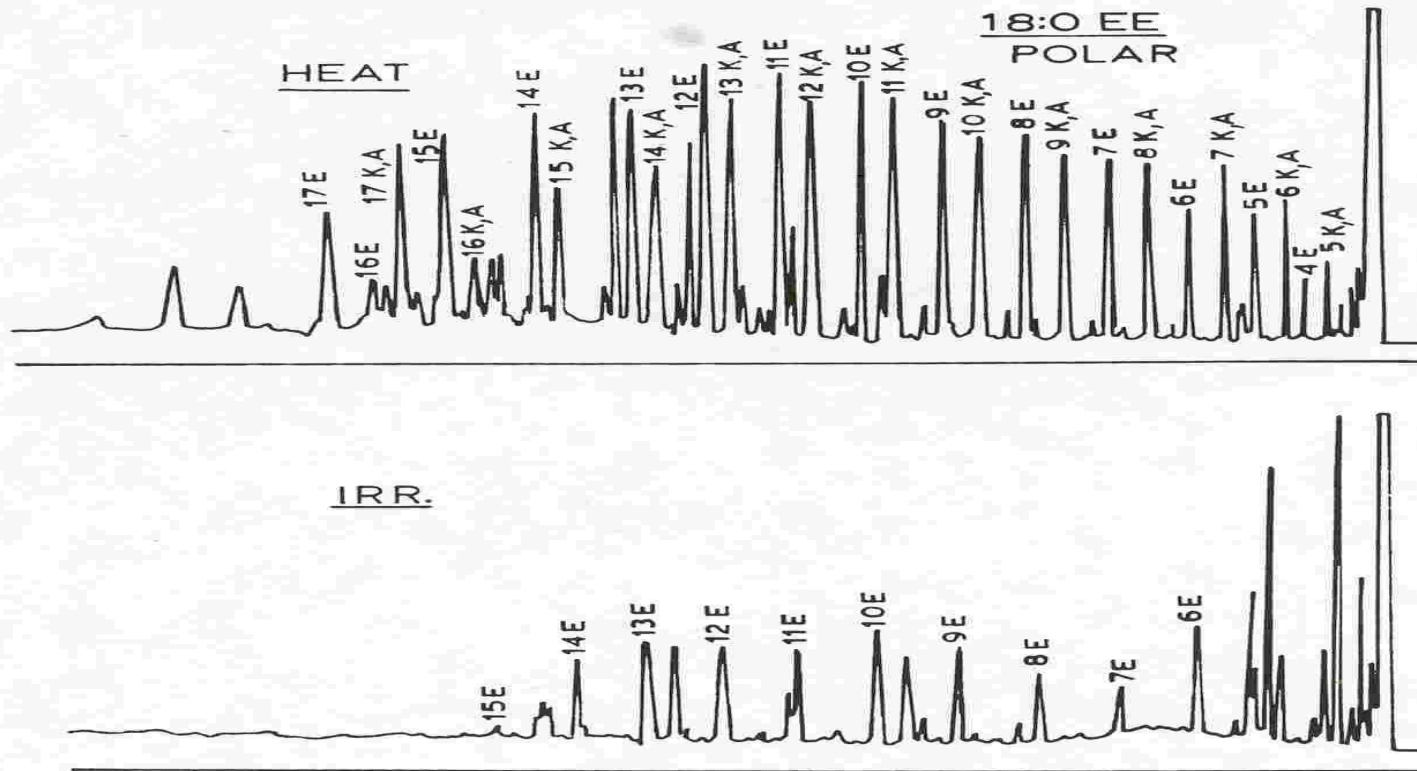
# Chemical Change

- Energy Stimulates Chemistry
- Increases When Liquid Present
- Initiates Reaction With Air
- Generally Little - But Not Necessarily Negligible - Change
- Can Be Controlled By Controlling Conditions

# Heated Lipid (180 °C/1Hr) vs Irrad (120 kGy)

74

NAWAR



**Figure 9.** The polar volatile compounds from ethyl stearate by heat (180°C, 1 hr) and irradiation (120 KGy). Numbers indicate carbon chain length. K, methyl ketone; A, alkanal; E, ethyl ester.

# Nutrition Issues

- Vitamins Can Be Labile to Heat and Irradiation
- Effects Most Significant at Medium Doses
- Must Distinguish Safety of Food From Safety of Diet
- No Issues Unique to Irradiation
- Generally Accepted that Irradiation Losses Should be Handled Like Heating Losses

# Microbiological

- Complex Organism More Sensitive Than Simple Organism
  - Mammals > Fresh Fruits or Insects > Single Celled Organisms > Viruses; (Prions Likely Resistant)
- Radiation Sensitivity Varies With Species
- Sensitivity Varies With Environment
  - Temperature; Water Activity; pH; Salt; etc
- Same Issues as Heat Processing



# Foods Permitted to Be Irradiated Under FDA's Regulations

■ All foods	Arthropod Control	1 kGy max
■ Dry Enzyme Preps.	Microbial Control	10 kGy max
■ Fresh Foods	Maturation Inhibition	1 kGy max
■ Spices/Seasonings	Microbial Control	30 kGy max
■ Poultry	Microbial Control	3 kGy max
■ Seeds for sprouting	Microbial Control	8 kGy max
■ Shell eggs	Microbial Control	3 kGy max
■ Meat and meat byproducts	Microbial Control	4 kGy/7 kGy
■ Molluscan shellfish	Microbial Control	5.5 kGy max
■ NASA	Sterilization	44 kGy min

# Other Irradiated Substances

- Medical equipment                      Microbial Control
- Laboratory animal                      Microbial Control  
    diets                                      50 kGy max
- Poultry feed                              *Salmonella* sp.  
    25 kGy Max
- Pet foods, treats and                      *Salmonella* sp.  
    chews                                      50 kGy max

# Active Ionizing Radiation Petitions

- Control of pathogens in crustaceans

  - *National Fisheries Institute*

- To control pathogens in a variety of multiple-ingredient products

  - *Food Irradiation Coalition*

# Active Petitions (Continued)

- To control microorganisms on nonrefrigerated meat food products
  - *USDA/FSIS*
  
- Amend poultry regulation to raise maximum dose and remove packaging limitation
  - *USDA/FSIS*

# Active Petitions (Continued)

- To control microbial contamination on dietary supplements, and ingredients used in the manufacture of dietary supplements
  - *Steris Corp.*
  
- Multi-ingredient shelf stable foods
  - *IBA*

# Labeling Criteria

- Misleading if it fails to reveal facts that are material in light of:
  - Representations made,
  - Consequences of use
- No statutory requirement specific to irradiation
- “Treated with radiation” or “Treated by irradiation”



# Labeling

- Congress Directed Reconsideration - 1997
- Advance Notice of Proposed Rulemaking  
Published February 1999
  - Cited Various Positions
  - Requested Comment on 15 Questions



# Labeling Status

- Lead Is With CFSAN's Labeling Group
- Comments Did Not Provide Clear Consensus or Rationale
- 2002 Farm Bill

# Controversy and Queries

## ■ Objections

- Consumer
- Public Citizen / Center for Food Safety

## ■ Formal Correspondence