

E-Beam Processing

Irradiation in The United States of
Fresh Produce and Perishables
Sadex Corporation
September 2, 2009

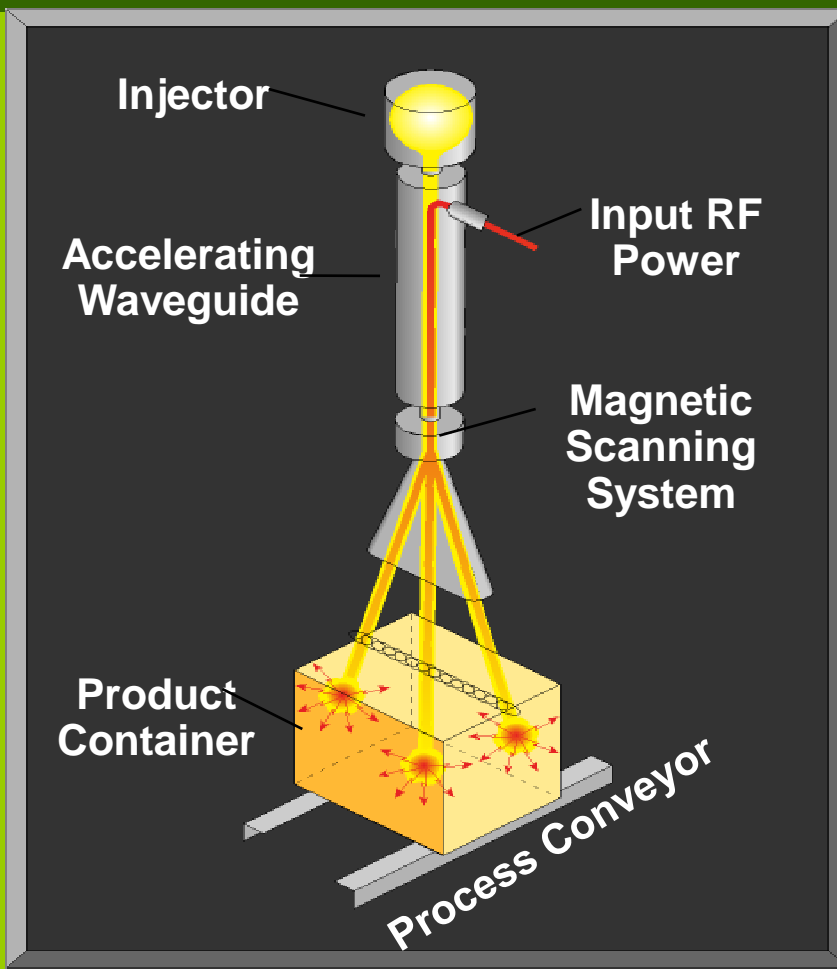
Objectives

- Introduce Sadex and the E-beam Irradiation Process
- Establish Purpose and Goals for Irradiation:
Product Safety, Reduce or Eliminate Pathogens and Harmful Pests, and Extended Shelf-life
- Answer Questions

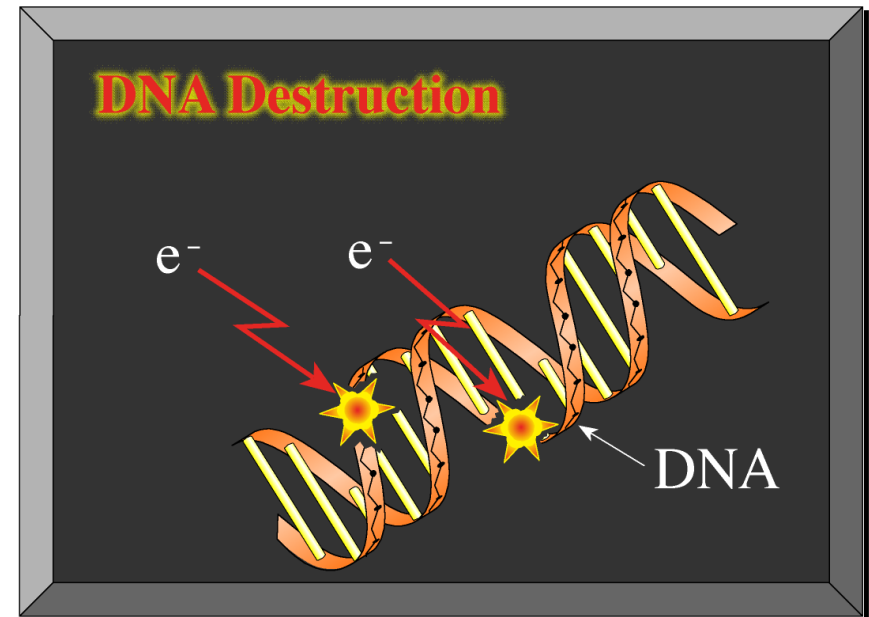
Patented Electron Beam System



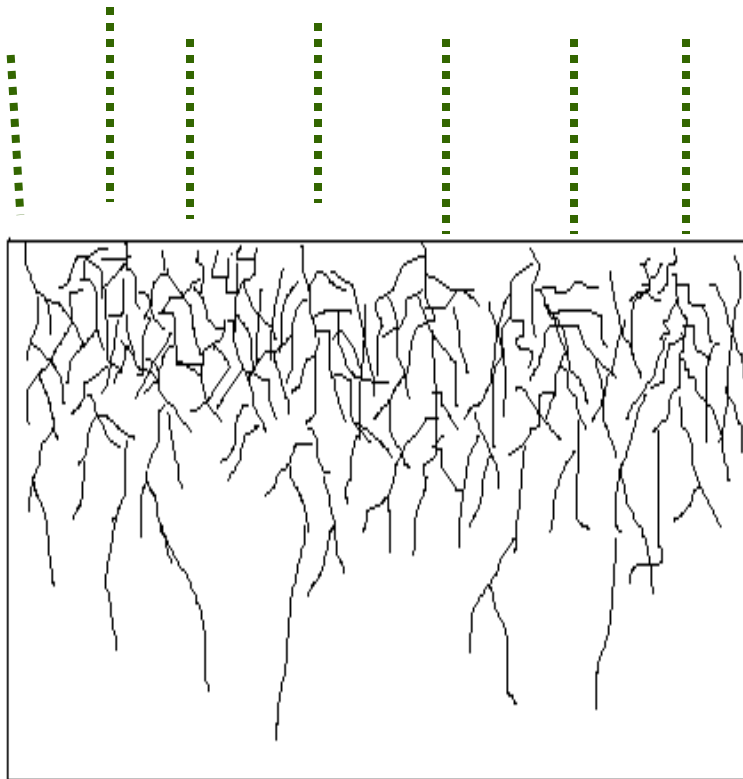
How does Electron Beam Pasteurization Technology Work?



Electrons disrupt the DNA chains either destroying or preventing reproduction by the organism

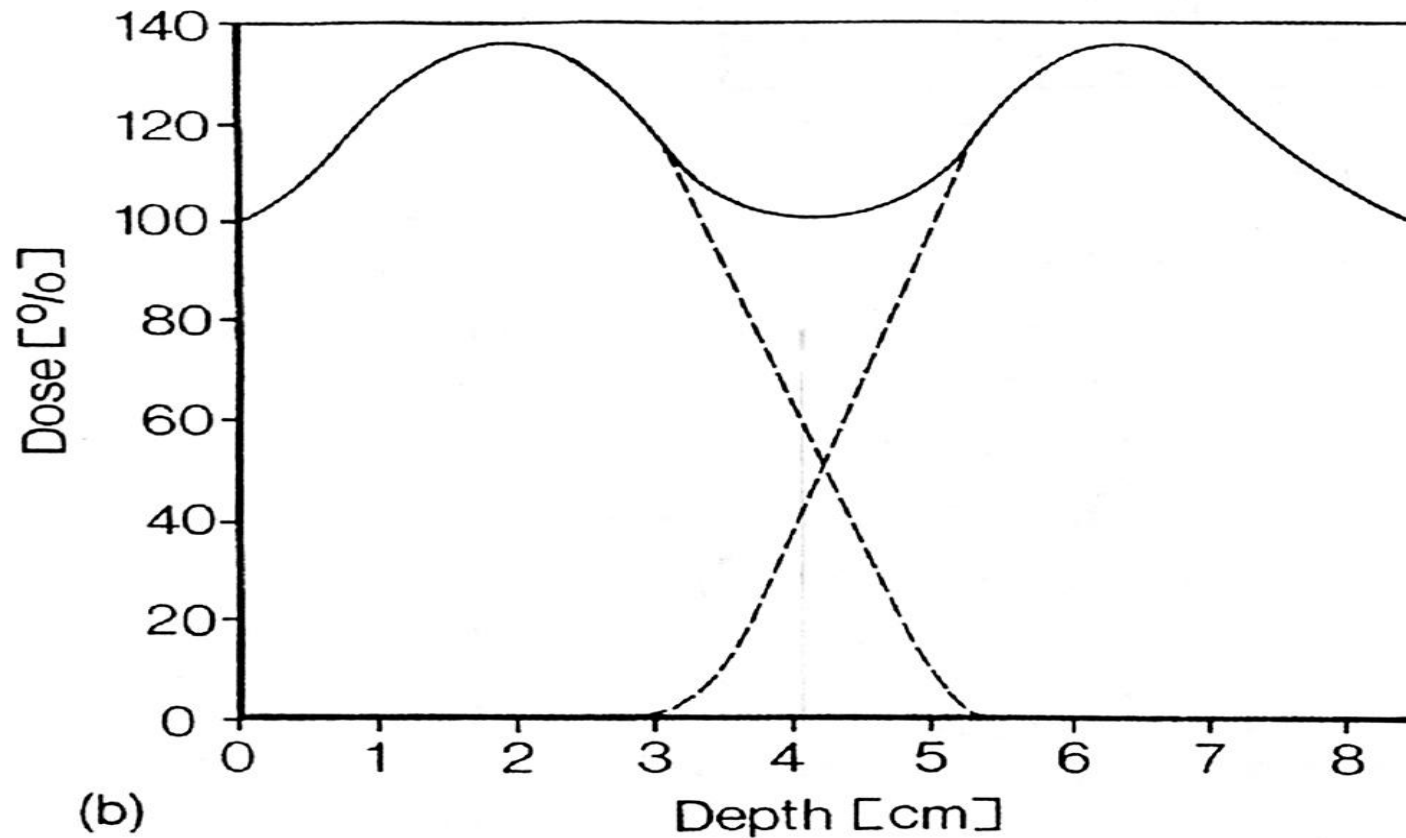


Electron Deposition



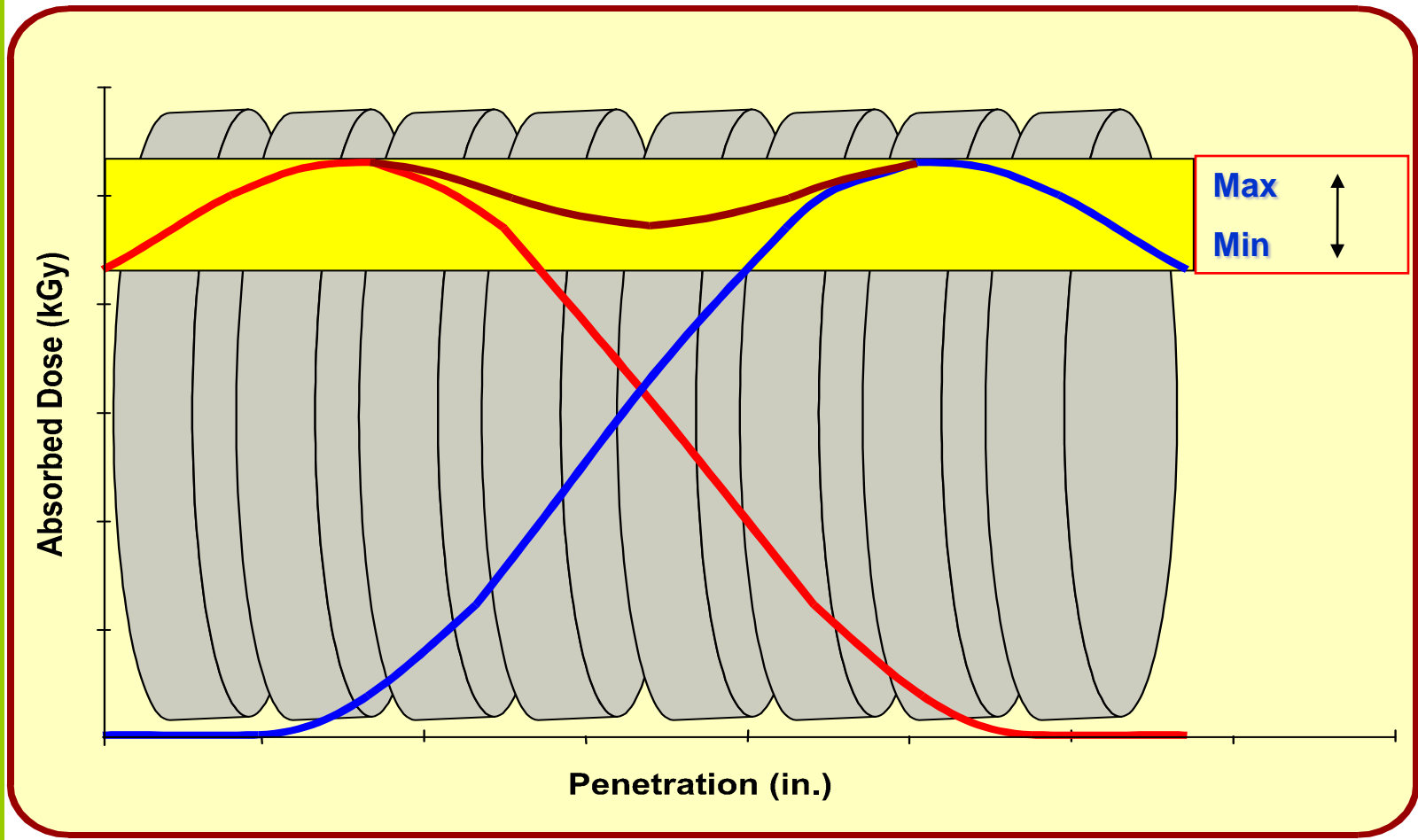
- Electrons strike electrons in the product (inelastic scattering) imparting a fraction of their energy into kinetic energy of the secondary electrons.
- All the electrons (primary and secondary) then suffer additional collisions until all their energy is dissipated by ionization.
- 1^o electrons → 2^o electrons → ionization

Depth Dose Distribution 10 MeV Electrons in Water



(b)

Dose Distribution (Max / Min)



Max:Min Ratio

- What is it?

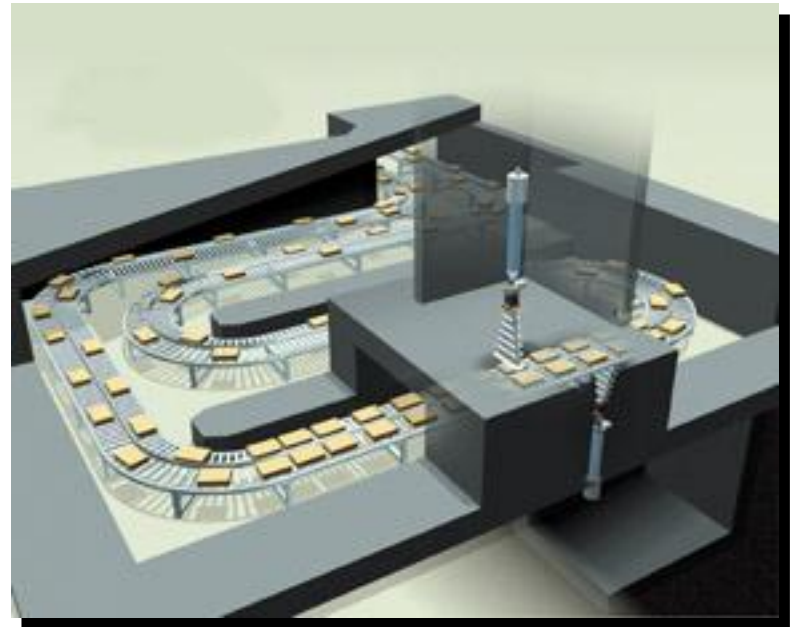
The ratio of the maximum dose absorbed by the product divided by the minimum dose

- Why is it important?

To achieve the necessary pathogen reduction, a minimum dose is required. If the max/min is too high you may exceed the FDA limits, or you may impact the organoleptic qualities of the product

Patented Electron Beam System

- Reduces or Eliminates dangerous bacteria and harmful pests
- Does not compromise food quality
- Extends shelf-life
- Refrigerated Facility Maintains Cold Chain
- Consumer friendly
- Uses commercial electricity
- Environmentally safe



Quality Control

- Refrigerated Facility: Cold Chain Management Throughout Process: Unloading, Handling, Treatment, and Re-loading
- Unit Count, Delivery Temperature, and External Damage Verified
- Processing Documentation/COA Available Upon Shipping
- Regulatory Compliance For Food Facility
- Customer's Determined Dose Delivery Guaranteed

Regulatory Compliance

- Facility is Fully Licensed and Regulated by On-Site USDA/FSIS Inspector
- Hazard Analysis Critical Control Point Plan (HACCP) USDA/FSIS required for processing meat/food products
- FDA/USDA Approvals In Place for Meat, Poultry, Fresh Produce, Spices, Shell Eggs, Animal Feeds, Feed Ingredients, Pet Treats, and Cosmetics
- Ag Marketing Service AMS Inspectors Available for School Lunch Program Products
- Homeland Security
- Center for Veterinary Biologics CVB
- FDA/USDA Dose Limits and Label Rules Apply
- FDA Approval is Pending for Other Products
- APHIS Approval and Inspection for Import/Export Products Pending
- Department of Public Health
- State Ag Dept.
- NIST, ASTM, RISO
- CODEX
- GMP's, SOP's, and SSOP's

Labeling and Packaging Update

- Irradiation Labeling Under Review by FDA if 'Irradiation' should be Required on Label
- All Contact Surface Packaging Material Polymers Approved for Irradiation by FDA either by CFR or Threshold of Regulation (TOR) up to 3 kGy or higher
- Produce Packaging Material Availability for Irradiation Limited Since Additives in Polymers Currently Not Approved

Iceberg Lettuce and Spinach Approved for Irradiation

- August 22, 2008 FDA Approved Irradiation up to 4.0 kGy for Pathogen Reduction and Extended Shelf-life of Fresh Iceberg Lettuce and Spinach, Stating Irradiation Safe 21 CFR Part 179
- GAO 2000 Report on Irradiation reduces Pathogens up to 99.9%
- FPA has RTE Petition Before FDA to Approve RTEs for Irradiation
- Petition Filed in 1999 but Held Up for Further Testing
- Produce from Foreign Countries and Hawaii is being Irradiated for Disinfestation and Consumer Acceptance is Good

Scientific Conclusions

- Process cannot make the product radioactive no matter how much dose is absorbed
- Compounds formed by irradiating food are the same as those produced by other processes
- Irradiation causes no toxic problems that adversely affect human health
- Only intervention to destroy internalized pathogens with the exception of cooking
- No Chemical Residue as from Fumigants and Chemical Interventions
- No evidence exists that pathogenic bacteria become stronger when irradiated

*“there is no other means to kill bacterium such as *E. coli* O157:H7 in raw ground beef” -USDA*

Questions ???

Should you have questions, please feel free to contact me at:

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