# Food Irradiation: FDA's Perspective

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# Federal Food, Drug, & Cosmetic (FD&C) Act


**Food Additives Amendment – 1958**

- Defines "food additive" (w/ GRAS exemption)
- Requires premarket approval of new uses of food additives, if not GRAS or otherwise exempt from the definition
- Establishes the standard of data review
- Establishes the standard of safety
- Establishes formal rulemaking procedures

*Food additive regulations are located in Title 21 of the U.S. Code of Federal Regulations (21 CFR)*

# FDA's Authority Over Sources of Radiation Used to Treat Food

- Section 201(s) of the FD&C Act defines the term "food additive" to include "any source of radiation intended for any such use"

- Foods containing unapproved food additives are considered adulterated under section 402 of the Act
  - Section 402(a)(7) – "a food shall be deemed adulterated if it has been intentionally subjected to radiation, unless the use of radiation was in conformity with a regulation or exemption in effect pursuant to section 409..."

# Basics of the Food Additive Petition Process

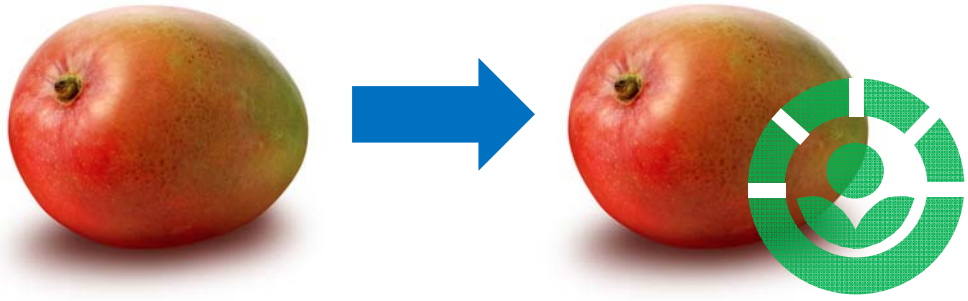
- FD&C Act requires premarket review of food additives
  - Safety Standard: Reasonable certainty of no harm
  - Petitioner: Burden to establish the safety of a proposed use
  - FDA: Responsible for conducting a full and fair evaluation
- Food additive petition requirements are found in Title 21 of the Code of Federal Regulations, Part 171.1 (21 CFR 171.1)

**An interested party petitions FDA** → **FDA reviews the data submitted** → **FDA makes a determination of safety** → Results in a regulation in 21 CFR

# Safety Considerations for Evaluating Sources of Radiation Used to Treat Food

Assess the impacts of ionizing radiation on:

- Safety of Radiolytic Products
  - Chemical Composition
  - Potential Toxicity
- Nutritional Adequacy
- Changes in Microbiological Profile



SAFE?

# Safety of Radiolytic Products: Impacts on Chemical Composition

- Radiation-induced chemical reactions:
  - Influenced by physical state of the food (solid, liquid, dry, or frozen) and dose
  - Extent of chemical changes are greater when water or oxygen is present
  - Radiolytic products formed are generally similar to chemicals produced during heating of food

***Petition should address the chemical changes resulting from the petitioned use of ionizing radiation***

# Safety of Radiolytic Products: Potential Toxicity

- Some chemicals may be formed that are of toxicological concern at high doses
  - These chemicals are also found in non-irradiated food at similar or higher concentrations (e.g., furan, alkylcyclobutanones)

- Hundreds of "toxicology" studies have been assessed
  - No effects noted in most studies
  - Studies that reported effects are mainly due to dietary deficiencies (i.e., abnormal diet for the animal)
  - Toxicology data for a treated food may be applied to the toxicological evaluation of a different, treated food of a similar generic class

# Nutritional Adequacy

- Minerals are not affected by ionizing radiation
- Irradiation of macronutrients has been well-studied
  - Protein
  - Lipid
  - Carbohydrates (to a lesser extent)
- Micronutrients are evaluated on a case-by-case basis due to variable sensitivity under different conditions
- Nutrient losses are considered in the context of the total diet

# Microbiological Considerations

- General microbiological considerations:
  - Sensitivity of the microorganism to ionizing radiation varies by species and with the environment
  - Petition should identify and address the pathogen of public health significance, if appropriate
- Specific microbiological considerations for phytosanitary use:
  - Dose levels above 1 kGy have the ability to affect the spoilage microorganisms

# Other Considerations: Scope

Image www.gandsorchards.com


Image www.wisegeek.org

Image sciencedaily.com

***Increasing Complexity***

# Other Considerations: Labeling

- As a condition of use, FDA requires that foods treated with ionizing radiation bear the radura label and must state on the label “Treated with radiation” or “Treated by irradiation”

# Other Considerations: Packaging

- Food should be packaged prior to treatment with ionizing radiation in a way to limit recontamination
  - Not all food will be contained in “closed” packaging (e.g., fruit)
- Packaging subjected to ionizing radiation incidental to the treatment of food shall be in compliance with one of the following:
  - 21 CFR 179.45
  - A threshold of regulation (TOR) exemption under 21 CFR 170.39
  - An effective food contact notification

# Petition for a New Use of Ionizing Radiation:

## Data Needed to Support Safety Determination

- Information relied upon may be:
  - Data generated by the petitioner
  - Data generated by a contract lab
  - Literature in peer-reviewed journals
  - Data in FDA's files obtained through a Freedom of Information (FOI) Act request
  - Other sources

- Data obtained on a food under specific conditions may be extrapolated to draw conclusions regarding the safety of similar food treated with ionizing radiation under similar conditions

# Pre-Submission Consultations

- OFAS encourages pre-submission consultations, including meetings, to facilitate the development of submissions
- Draft petitions may be shared with OFAS
- Pre-submissions may be used:
  - To verify whether a submission is required to a certain program;
  - To determine whether the quality and quantity of information is adequate;
  - When there are uncertainties on how certain data may be interpreted; or
  - To assess a study protocol

***We recommend petitioners consult with OFAS prior to initiating studies***

# Resources

- FDA's website (fda.gov):
  - Webpage for Food Irradiation: http://www.fda.gov/Food/IngredientsPackagingLabeling/IrradiatedFoodPackaging/default.htm

- The Electronic Code of Federal Regulations (see Title 21, Part 179)
  - www.ecfr.gov

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