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FDA
10 March 2021

Focus:

U.S.

Regulations



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)



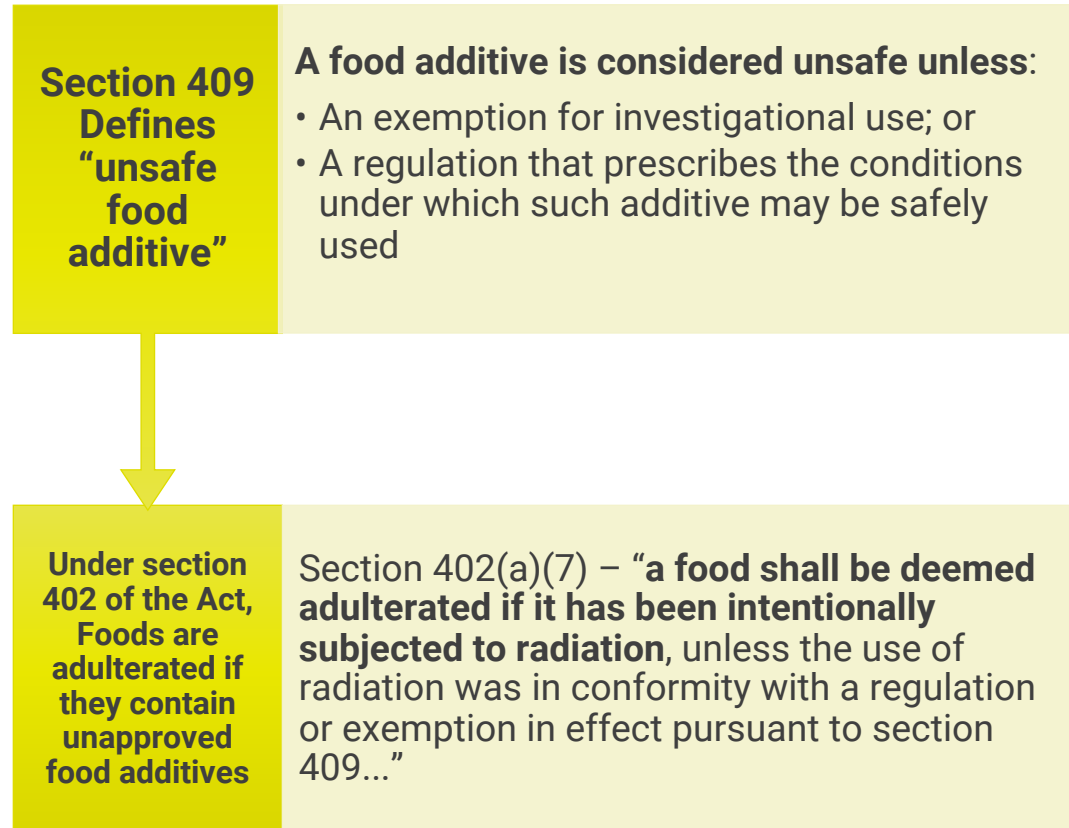
Definition: Food Additive

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**)**



Source: FDA's Authority over Food Irradiation





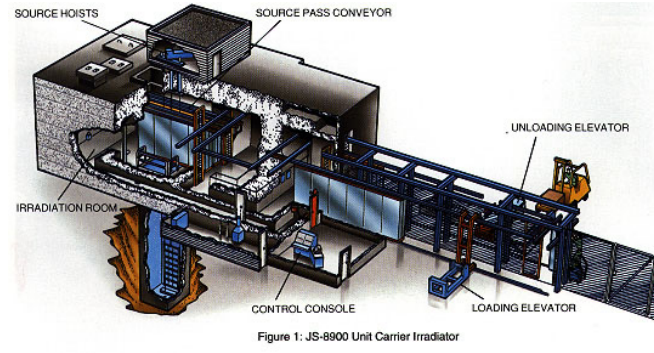
FDA's Premarket Approval Authority

- ❖ In order to approve a food additive, FDA must conclude its use is safe and issue a regulation.
 - ❖ FDA's safety standard is "reasonable certainty of no harm..."
- ❖ The burden of establishing the safety of the proposed use is on the petitioner
- ❖ FDA conducts a full and fair evaluation of the relevant scientific data and information

FDA evaluates the additive's intended technical effect, but does not consider possible benefits

FDA's Regulations:

Which foods may currently be treated with ionizing radiation (21 CFR 179.26)

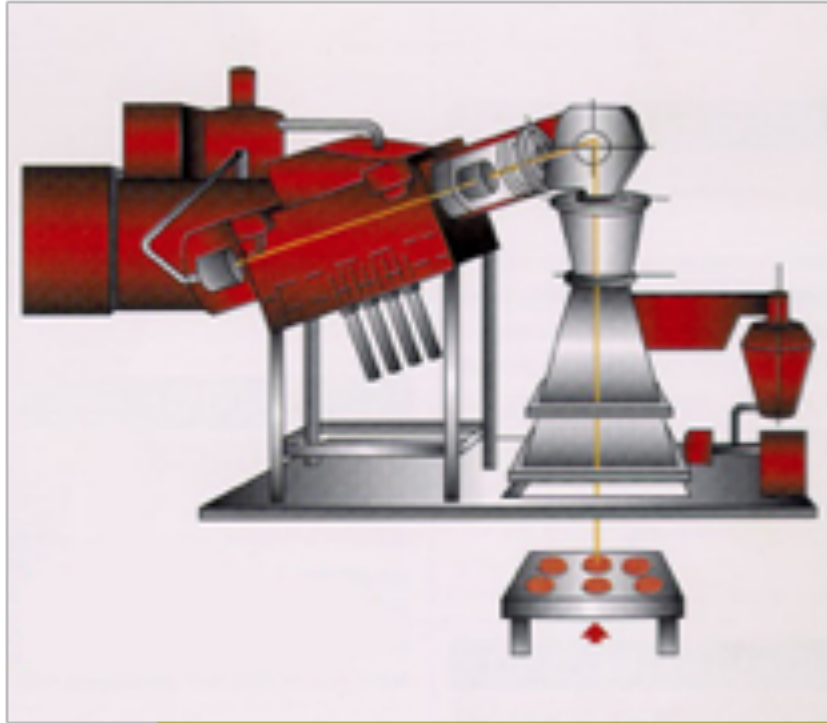


Category	Use/Dose
➤ All foods	Arthropod Control 1 kGy max
➤ Dry Enzyme Preps.	Microbial Control 10 kGy max
➤ Fresh Foods	Maturation Inhibition 1 kGy max
➤ Spices/Seasonings	Microbial Control 30 kGy max
➤ Poultry	Microbial Control 4.5 kGy/7 kGy
➤ Seeds for sprouting	Microbial Control 8 kGy max

Category	Use/Dose
➤ Eggs	Microbial Control 3 kGy max
➤ Meat and meat byproducts	Microbial Control 4.5 kGy/7 kGy
➤ Molluscan shellfish/ crustaceans	Microbial Control 5.5 / 6.0 kGy max
➤ Fresh lettuce and spinach	Microbial Control 4 kGy max
➤ NASA	Sterilization 44 kGy min

FDA's Regulations: Ionizing sources that may be used to irradiate foods:

- Cobalt 60 – 1.33 MeV
- Cesium 137 – 662 keV
- Electron accelerators operated at 10 MeV or less
- X-ray generators operated at 7.5 MeV or less



Labeling

- The 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**”





Web Based Information Resources

Food Safety and Irradiation

- [Code of Federal Regulations – 21 CFR179 – Irradiation In The Production, Processing And Handling Of Food](#)
- 21 USC § 321(s) – [Definition of a Food Additive](#)
- FDA – [Food Irradiation: What You Need to Know](#) –
- USDA – [Irradiation and Food Safety Answers to Frequently Asked Questions](#)
- Food Safety – [Food Safety dot gov](#)
- Food Irradiation org – [Food Irradiation](#)

Questions?





Thanks.

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