Status of Irradiated Foods in the USA

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Introduction

The concept of food irradiation is over 100 years old. The British patent for the use of ionizing radiation for improving the "keeping quality" of foods was issued in 1905. The US patents for ionizing irradiation for preserving foods was issued beginning in 1918 for preserving organic materials using X-rays. In 1963, the US federal government approved the use of ionizing radiation for treating wheat and flour. Since then a number of different foods have been approved for irradiation in the United States. These include fresh and frozen ground beef, poultry meat, spices, shellfish, fresh-cut spinach and lettuce, etc. However, there is a sense that this technology is nowhere close to be used to its fullest potential. The food industry blames the government for not enough approvals while the government in turns points out that the food industry has not utilized the approvals already in place. The ultimate result is that consumers today do not have adequate choice in the market place for foods that are guaranteed to be free of foodborne pathogens. There are a number of factors that are responsible for the current situation. This chapter presents an overview of the current status of irradiated foods in the United States and then in the latter half of the article highlights some of the major challenges facing food irradiation in the United States. Though the article focuses on the U.S., the reader would notice that many of these issues are applicable to many regions of the world.

Food Irradiation Regulations in the United States

Food safety in the U.S. is governed and managed by two federal agencies namely the United States

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Department of Agriculture' s Food Safety Inspection Service (USDA-FSIS) and the United States Food and Drug Administration (FDA). The USDA-FSIS authority extends over the meat and poultry industries while the FDA is responsible for all other types of foods such as milk, prepared foods, fresh-cut vegetable produce, seafood, shellfish, spices etc. In addition to the food safety authority of the FDA and the USDA-FSIS, another federal agency USDA-APHS (Animal and Plant Health Inspection Service) is responsible for irradiation technology approvals that governs the control of insect and pests during the shipment of fruits and vegetables across the US borders. The delegation of responsibility across these federal agencies has been the subject of a lot of criticism and confusion. Though there has been a popular push to merge the FDA and the USDA, it does not appear that this merger will take place. The US Congress recently passed the Food Safety Modernization Act in 2010 to address the public' s growing concern about food safety and to address large scale food borne disease outbreaks. The newly enacted law does not call for the merger of the USDA and the FDA. Irrespective of which agency controls food safety, the US has the largest number of food irradiation approvals in the world (Table 1). The list of foods that have been approved for irradiation is quite remarkable. However, there are a number of foods that are currently not been approved for example, prepared foods,fresh produce such as carrots, peppers, tomatoes etc. The government approvals for specific food items are based on 'petitions' that are submitted by interested entities namely food manufacturers, food processors, etc. Though petitions for foods such as ready-to-eat (RTE) (prepared foods) have been submitted to the FDA, the FDA has yet to make final decisions on these petitions.

As seen in Table 1, the maximum permissible doses vary depending on the food and the intended purpose of application. In the US, food irradiation is considered to be a "food additive". Food irradiation though in reality is a food processing technology and not a "food additive". There were some complicated bureaucratic reasons behind the reason why food irradiation was classified as a food additive by the US Congress in 1958. Nevertheless, this definition currently governs food irradiation in the United States. The designation of irradiation as a "food additive" results in

Table 1: Foods that are currently permitted to be irradiated in the United States

Food	Purpose	Maximum Allowable Dose
Fresh, non-heated processed pork	Control of *Trichinellaspiralis*	0.3 kGy min. to 1 kGy max.
Fresh foods	Growth and maturation inhibition	1 kGy max.
Foods	Arthropod disinfection	1 kGy max.
Dry or dehydrated Enzyme preparations	Microbial disinfection	10 kGy max.
Dry or dehydrated spices/seasonings	Microbial disinfection	30 kGy max.
Fresh or frozen, uncooked poultry products	Pathogen control	3 kGy max.
Refrigerated, uncooked meat products	Pathogen control	4.5 kGy max.
Frozen uncooked meat products	Pathogen control	7 kGy max.
Fresh shell eggs	Control of *Salmonella*	3.0 kGy max.
Seeds for sprouting	Control of microbial pathogens	8.0 kGy max.
Fresh or frozen molluscan shellfish	Control of *Vibrio* species and other foodborne pathogens	5.5 kGy max.
Fresh iceberg lettuce and fresh spinach	Control of food-borne pathogens, and extension of shelf-life	4.0 kGy max.

specific labeling requirements. The FDA issued a number of irradiation approvals between 1984 and 2000. Since 2000, the FDA has approved the use of irradiation for fresh-cut spinach and lettuce and for shellfish. Petitions for other foods such as prepared foods, crustaceans, nutritional supplements, etc., are still pending.

Food irradiation can be accomplished in the US by either 1.3 MeV cobalt-60, 662 keV Csium-137, 10 MeV (or lower) Electron Beam or 7.5 MeV (or lower) X-ray sources. It may be important to keep in mind that the internationally mandated Codex rules only allows up to 5 mEV X-ray sources for X-ray irradiation. The ability to use machine generated ionizing radiation such as E-Beam or X-ray has made a significant impact on the attractiveness of this technology for the food industry for the different applications. As seen in table 1, the maximum permissible doses vary from commodity to commodity. What is evident fromTable 1 is that nearly all foods can be irradiated up to 1 kGy as long as only growth and maturation inhibition can be claimed. In other words, it is possible to irradiate fresh fruits and vegetables as long as only shelf life extension or arthropod disinfection can be claimed.

Ionizing radiation technology has gotten a boost in the United States ever since the federal agency USDA-APHS has approved the use of ionizing radiation for phytosanitary applications. Today, countries such as India, Mexico, Pakistan, Ghana, Vietnam, Thailand are able to export agricultural commodities to the United States by employing this technology. India and Pakistan are making considerable investments in their countries to exploit this technology to ship mangoes. Mexico uses this technology to ship guavas and mangoes. Vietnam and Thailand are using this technology to ship litchi, rambutan and other exotic fruits (dragon fruit) to the U.S. The use of ionizing radiation is allowing countries that have historically used other disinfestation technologies such as hot-water dips,

Table 2: Technology options currently available for Mexican agricultural commodities for export to the U.S.

Commodity	Irradiation	Cold Treatment	Methyl Bromide	High Temp. Forced Air	Vapor Heat	Hot Water Dip
Apple		X				
Carambola	150Gy					
Cherry		X				
Grapefruit	150Gy	X	X	X	X	
Guava	400Gy					
Mango	150Gy			X	X	X
Nectarine		X				
Sweet Lime	150Gy					
Sweet orange	150Gy	X	X	X	X	
Peach		X				
Manzano Pepper	150Gy					
Plum		X				
Tangerine/Clementine/Mandarin	150Gy	X		X		
Yam			X			

freezing, ethylene bromide , vapor heat etc to switch to ionizing radiation technology. From the current trend it appears that only ionizing radiation will be approved as the treatment choice for addressing insect and pests in imported cargo. Table 2 shows the commodities and the technologies that are currently available to treat agricultural commodities from Mexico prior to export to the United States. As can be seen from Table 2, only ionizing radiation can be used to treat for example, manzano peppers, sweet lime, carambola, guavas etc.This technology has now allowed US consumers the ability to purchase fruits from different corners of the world. Many of these products are sold at retail stores and do carry the "radura symbol".

The USDA-APHS has a very systematic approach as to how they interact with governments from around the world in getting the necessary approvals needed for the different commodities and different countries. USDA-APHS not only approves the technology but is very intimately involved in granting permits to commercialirradiation facilities located in the US and abroad.

Commercial Food Irradiation in the United States

It has been estimated that in the US alone, approximately 80,000 metric tons (~175 million pounds) of spices, 8,000 metric tons (~ approximately 18 million pounds) of ground beef, and 4,000 metric tons (8 million pounds) of produce (for phytosanitary purposes) are irradiated today. These numbers are no doubt very small compared to the total production of spices and ground beef that is in commerce. However, what is important to know is that irradiated foods and products are commercially available in the U.S. Today, almost 100% of all food irradiation in the US are based on the service center model. In this model, food producers ship their products to a central service center where it is irradiated and thereafter shipped to distributors/stores. Sadex, Inc (located in Iowa), Food Services Technology (located in Florida) and the National E-Beam Center at Texas A&M University (located in Texas) are the only facilities performing ground beef irradiation. The X-ray facility located in Hawaii (Hawaii Pride) is primarily focused on treating sweet potato, papaya and dragon fruit.

In the United States, the National Academy of Sciences published a report in the early 2000's that due to the concern of nuclear terrorism, there should be a serious and systematic effort to reduce the commercial use of radioactive isotopes such as cobalt-60 and cesium-137. machine sources such as E-Beam linacs continue to be built at a slow moderate pace. According to some estimates, though E-Beam occupy only 7% of the market share of the irradiation business, this share is growing significantly. However, most of the installed E-Beam capacity is being targeted for the medical device sterilization sector.

Consumer Acceptance of Irradiated Foods in the United States

It has been incorrectly assumed that US consumers will not purchase irradiated foods. This is a grossly erroneous statement. Since 2000 when irradiated foods became available quite extensively there has not been any consumer backlash against these products in grocery stores. On the contrary, the popularity of these products actually increased between 2000 and 2002. In 2002 there were at least 2000 stores that carried irradiated foods. In 2002, the main supplier of irradiated foods (SureBeam, Inc) filed for bankruptcy and the interest among store owners declined, A number of peer-reviewed studies have been published that have conclusively shown that consumers not only are accepting of irradiated foods when information is accurately presented but are also willing to purchase these products at a higher price. Today, irradiated spices, irradiated fresh ground beef, irradiated frozen ground beef, irradiated mangoes, irradiated guavas, irradiated papaya, irradiated dragon fruit, irradiated litchi, and irradiated rambutan are available in grocery stores and from online stores across many parts of the U.S.These products have the "radura" symbol placed on the "country of origin" or product locator unit (PLU) stickers. It is important to keep in mind that no irradiated product has ever been removed from the shelves because of consumer resistance. Thus, the argument "consumers will not buy", or there are consumer acceptance issues are pure anecdotal references that is not supported by any empirical evidence.

Challenges Facing Food Irradiation in the United States

There are multiple challenges or hurdles that stand in the way of greater adoption of this technology in the U.S such as

Lack of understanding among decision makers:There is a stunning lack of understanding among many in the food industry of what this technology is, what this technology is not, what does it take to adopt this technology, and how does one adopt this technology is a profit-sustainable manner. There is no doubt that the food industry knows the potential of this technology. However, what they are unable to still understand is how do they exploit this technology in their context of a business. What are missing are business models that help with the adoption of this technology for the different producers, distributors and retailers. Who has the vested interest or the potential return of investment from this technology?

Lack of business models: There are no business models for the ground beef industry, the seafood industry, the fresh produce industry or even the ingredient industry that include an irradiation step. Today, most of the food irradiation is done using so-called service facilities to which companies send their products for treatment. This approach may work for maybe half a dozen companies. However, because of the logistics this was never meant to be the only model for adopting irradiation.For this technology to gain widespread use among the food industry, business models have to be developed and tested that clearly identify the required capital investment, expected profit margins, and potential threats. These models have to be developed and validated based using multiple scenarios.Another key issue that is a barrier to the adoption of this technology is the cost and who is willing to pay for this technology cost? Whether it is cobalt-60 or E-Beam/X-ray irradiation there are significant costs that are involved. These costs can be up-front costs, operating costs, or the costs associated with transportation, storage and disposal of radioactive material. There are no business models to understand who stands to gain the most, and hence who has the vested interest to invest in this technology. Business models that incorporate the new metrics have to be developed for the different types of food industries.

Lack of packaging standards: The conventional wisdom has been to use this technology for processing large volumes of product quickly in an irradiation facility. This argues for using this technology to process large pallets or crates. However, this bulk processing is contradictory to what the reality is today in the market place. Today, foods especially fresh fruits and produce are sold in either single or small serving sizes with the product often cleaned, cored, sliced, and packaged as a snack or convenience food. If this is the reality today why are irradiation technology providers still advocating high product throughput as the key price point? Why should a processor or distributor or retailer invest in a facility that is designed primarily for bulk processing? Are the current packaging material used in such single serving/small serving packages compatible with the federal approved packaging material? It would appear that the smaller packaging design would be suitable for E-Beam processing. However, experimental data that the industry could use is severely lacking.

Improved consumer surveys: Enhanced consumer survey instruments need to be designed to capture the type of information that is really needed for the decision makers to understand the value of this technology. Outreach and educational materials that no longer focus on this technology as just a "pathogen-kill" technology have to be developed. There is a strong un-fulfilled demand for these tools. The outreach materials to different audiences such as corporate decision makers, corporate legal department, corporate risk reduction officers, investment bankers, etc need to carefully thought through and developd with input from the target audience members.

Lack of irradiation capacity and trained personnel: If the FDA and the USDA approved the use of irradiation technology for all different types of foods there is absolutely not enough capacity of irradiators in the country to serve the irradiation needs. The relative scarcity of this technology has also resulted in an extremely small pool of trained individuals that are involved in different roles such as those who are qualified to operate and service the instruments and qualified to serve as dosimetrists. This lack of installed capacity and manpower is a serious issue in the US.

The National Center for Electron Beam Research at Texas A&M University focuses its efforts to address many of these challenges.

National Center for Electron Beam Research at Texas A&M University

The National Center for Electron Beam Research (www.ebeam.tamu.edu) serves as an un-biased venue for academic, government, and industry scientists to carry out strategic electronic pasteurization and sterilization research using Electron Beam (E-beam) and X-rays.

The goal of this Center is to provide academic and industry scientists with a unique technology platform to carry out strategic E-Beam and X-ray related pasteurization and sterilization research to protect and enhance the value of foods, food ingredients, for drinking water and wastewater treatment, to enhance the value of agricultural and horticultural products, develop new synthetic materials, and develop the efficacious vaccines (Figure 1). The Center brings together academic, industry, and government researchers from across the United States and overseas to exploit E-Beam and X-ray technologies to benefit mankind in different areas. The mission statement of the Center is *"Harnessing E-Beam and X-ray technologies to Improve Human Life"*. The Center is committed to building strong partnerships with the government and private industry in our efforts to move the technology from the research laboratory to the market-place.

The activities of the Center hinge around of the world's largest, high-throughput research and commercial level E-beam and X-ray irradiation equipment. The E-Beam and X-ray irradiation equipment is housed in a 16,000 sq. feet dual modality (E-Beam and X-ray) facility on campus that has 2 vertically mounted 10MeV, 18 kilowatt E-Beam Varian linear accelerators and one horizontally mounted 5MeV, 15Kilowatt X-ray Varian linear accelerator. The facility utilizes a single conveyance system to move the product in and out of the process chamber (Figure 2) All LINACs and conveyers are controlled with Allen Bradley Programmable Logic Control (PLC) software.The rated capacity of the irradiation facility is approximately 12,000 - 15,000 pounds of product per hour. Additionally, a dosimetry laboratory equipped with alanine and radio-chromic film dosimetry support the activities of the Center.

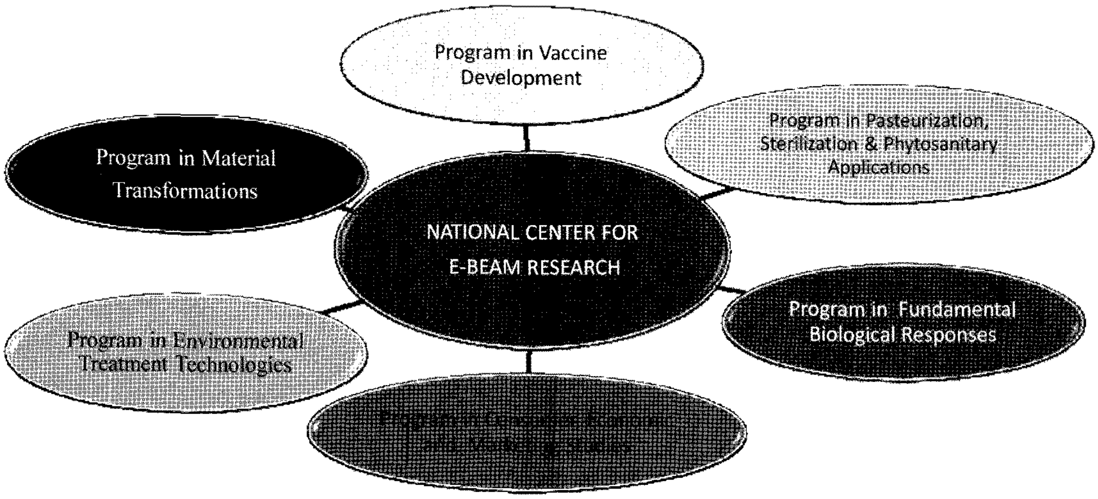

Fig. 1. Programmatic Areas within the National Center for Electron Beam Research at Texas A&M University

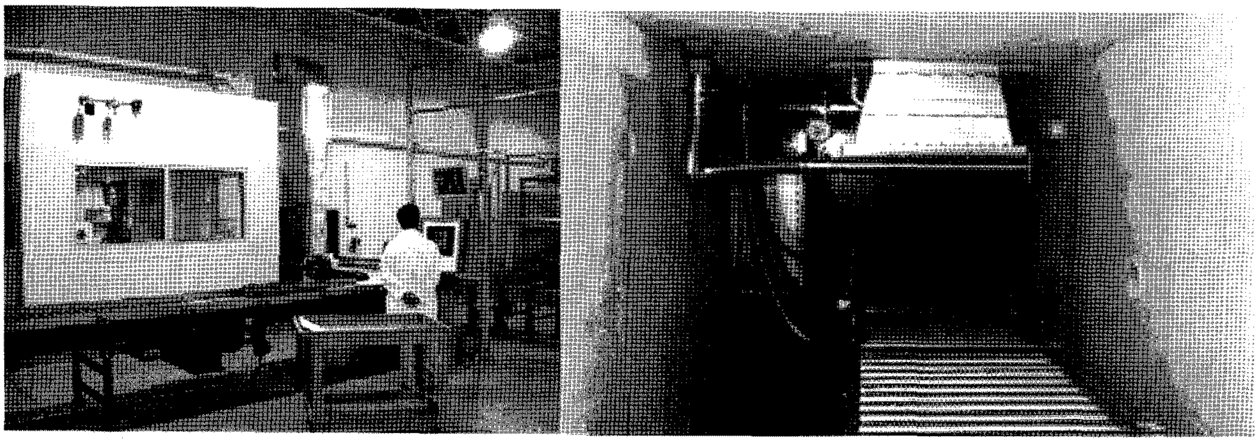

Fig. 2. Views of the product conveyor system and the irradiation cell showing the E-Beam "horn" from the top and the X-ray "horn"from the side

Very importantly, we also serve as a training and teaching facility for industry scientists, graduate and undergraduate students and visitors from around the world. We work in close collaboration with a number of leading national and international agencies such as the International Atomic Energy Agency (IAEA), NASA, FDA and the USDA. We also have a number of collaborative linkages with private industry and academic institutions from around the world. We organize annual hands-on workshop at the Center each year in April. The 2011 workshop was a major success based on the response we had for the workshop, the attendance and the evaluations. We do not complain about the slow adoption of E-Beam technologies. We are trying to empower individuals and institutions for the 21st century with meaningful information.