Food Irradiation for Fresh Produce

by Edward Groth III, Ph.D.

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Executive Summary

Growing interest in irradiating produce

Two outbreaks in late 2006 of food-borne illness involving *E. coli O157:H7* on spinach and lettuce have intensified the sense of urgency about reducing the risks of pathogens in fresh produce. Members of the produce industries, government regulatory agencies and consumers all share the desire to take effective steps to eliminate or sharply reduce risks from *E. coli* and other produce-born disease-causing organisms.

In the current climate, interest has grown in the possibility that food irradiation, a long-available technology already being used as an anti-bacterial treatment for some poultry and ground beef, could be applied to mitigate problems associated with human pathogens in fresh fruits and vegetables. Irradiation has also been used to kill insects in and extend shelf life of some fresh produce, but it has not been applied to control pathogens in those foods. Some advocates have recently claimed that irradiation could have solved produce safety problems long ago, if its use had not been inhibited by political opposition and industry and government timidity. But the facts are much more complex.

Current status of irradiation for fruits and vegetables

While irradiation in theory has a significant potential to enhance produce safety, its use for this purpose first needs to be approved by the US Food and Drug Administration. A petition seeking such approval was submitted to the FDA by a food industry coalition in 1999, but approval has not been granted yet. The basic reason for this delay is a lack of good scientific information on critical issues the FDA would have to resolve in order to conclude that irradiation of produce is effective and safe.

While irradiation can undeniably kill food-borne bacteria, radiation at doses useful for that purpose can adversely affect the sensory quality of foods. Early studies of irradiated fruits and vegetables indicated that these fresh, plant-derived foods are more sensitive to radiation damage than meats, spices, or grains. In fact, the doses of radiation required to reduce pathogen levels to effectively safe levels generally caused unacceptable sensory damage in fresh produce. For many years it was therefore assumed that fresh fruits and vegetables, and related products like nonpasteurized fruit juices and pre-cut salads were not suitable candidates for food irradiation.

Promising recent research, but much more still needed

With growing awareness of the magnitude of pathogen contamination of produce, that conclusion is being reassessed. Research in the past decade or so has explored the use of lower doses of irradiation on fresh produce, to find out whether acceptable reductions in pathogen loading can be achieved while preserving the taste, aroma, color and texture of the foods.

This still relatively small field of research has produced some promising evidence that it may be possible, in many cases, to strike the right balance between pathogen reduction and preserving produce quality. Particularly if irradiation is combined with other anti-microbial treatments and food preservation steps, recent studies suggest that irradiation may eventually be usefully applied to some current produce-pathogen problems. However, this same research indicates that applying food irradiation to a particular food-pathogen combination requires knowledge about a large number of parameters that affect the results of irradiation. The problems are complex, and research to date has identified many needs for additional and better data. Without the FDA's approval, a horse-and-cart problem exists: There is no current market for irradiated produce, and therefore minimal economic incentives to spend the money to answer the challenging scientific questions that need to be answered to support both an FDA decision and commercial-scale produce irradiation. Although food irradiation is used in several other countries, research needed to implement it here is likely to advance slowly, and produce irradiation will probably not be commercially practical in this country for years, unless the situation changes radically.

Safety steps are needed now

Given the urgency of reducing risks from pathogens in produce, the industries and the regulatory agencies involved cannot wait for irradiation to arrive like a deus ex machina to solve these problems. Instead, those stakeholders must act now, using available Good Manufacturing Practices (GMP), Good Agricultural Practices (GAP) and safety systems such as Hazard Analysis by Critical Control Points (HACCP). These well-tested, feasible risk-reducing measures can undoubtedly be more effectively applied than they have been to date (guided by some well-focused research), and should significantly reduce the risks from produce-borne pathogens.

The clear choice for the produce industries today is to move ahead forcefully and rapidly with proven, currently available risk-reduction measures. Research may eventually show that irradiation of produce is feasible, effective and worth doing as an added safety step in specific cases. But by the time research gets that far, many of these problems may already have been solved by other means.

The critical scientific and practical questions

This report examines the research topics on which more extensive data are needed to determine how useful food irradiation might be as a partial solution to produce safety problems. The topics covered include:

How effectively can irradiation reduce pathogen loads on fresh produce?

Laboratory research to date suggests that irradiation can reduce pathogen populations on fruits and vegetables of various types by about 100- to 100,000 fold. Irradiation of meats has been reported to cut bacterial loading by 100- to 1,000,000-fold. The criterion for effectiveness for processes like heat pasteurization, used to control pathogens, is at least a 100,000-fold reduction. A critical question is clearly whether the generally lesser pathogen reductions attainable on irradiated produce make the foods "safe enough."

The available studies also show that the degree of reduction of bacterial populations depends on many factors, including the type, variety and physical characteristics of the foods involved; the type of radiation used; the strain of bacteria; how well the particular food supports re-growth of the bacteria that survive; how long and at what temperatures the food is stored after irradiation; and numerous other variables. Irradiation protocols must be carefully tailored to fit the specific needs of specific food-pathogen combinations under specific conditions. There is no one-size-fits-all approach. Research is needed both to develop applications for specific problems, and to determine whether results obtained in controlled laboratory experiments can be replicated on a commercial scale.

Will irradiated produce retain acceptable sensory quality?

Recent research suggests that irradiated fruits and vegetables can often have acceptable sensory quality, although the low doses required to preserve food quality may provide bacterial load reductions that are less than optimal. The most promising approaches combine low-dose irradiation with other anti-bacterial treatments (e.g., warm-water dips, modified atmosphere packaging) or with other food preservation techniques (e.g., adding sorbic acid to irradiated juices).

Available studies have found no serious loss of sensory quality (flavor, texture, aroma, and appearance) for many fresh fruits and vegetables tested with such regimes. However, more extensive research is still needed to determine

the best combinations of measures and irradiation doses for specific produce varieties and pathogens. Results are likely to be highly specific to food variety, pathogen and other aspects of the problem to be solved. Given the complexity of sensory quality, developing the needed data poses a considerable research challenge.

Is irradiated produce safe to eat?

Many expert authorities have reviewed the evidence over the years, and concluded that irradiated foods do not pose significant health risks to people who eat them. Some important scientific uncertainties remain, though, and some new safety questions related specifically to irradiation of fruits and vegetables still need to be evaluated. Recent studies indicate that irradiation of high-carbohydrate foods, such as fruit juices, creates small amounts of furan, a chemical that causes cancer when fed at high doses to lab animals. Amounts formed by irradiation are very small, and less than amounts formed when foods are cooked, but more data are needed.

Concern also exists that irradiating fruits and vegetables in their packaging (the preferred method, as it prevents post-irradiation bacterial recontamination) could make chemicals from packaging materials migrate into foods. Some packaging materials used for produce today have not been tested for this potential problem, and research is needed on effects of irradiation at realistic doses on specific foods in their likely actual packaging.

Does irradiation of produce have other disadvantages?

Awareness that fruits and vegetables were going to be irradiated, or had been irradiated, might dispose people at all steps from farm to table to be less attentive to proper sanitation procedures. For example, growers and processors might apply GAP and GMP less aggressively, or retailers and consumers might neglect proper refrigeration in the mistaken belief that irradiated foods were sterilized. If so, irradiation could devolve from being one additional safety measure (its proper role) to become an end-of-the-line "clean-up" for a sub-optimal production process, or it could generate a "false sense of security" in the safety of irradiated produce. No one wants these outcomes to occur, but they are reasonable concerns and would need to be addressed through stakeholder education programs.

Is irradiation of produce economically feasible?

Although food irradiation facilities cost millions of dollars to build and operate, they would not need to be built specifically to irradiate fruits and vegetables. If the FDA approves produce irradiation, members of the industry could use existing facilities (those that irradiate meat, for instance). There would be significant logistical challenges—transporting crops to and from irradiation sites, funneling produce through irradiation during the intensity of a harvest season. It seems likely that irradiated produce would cost more than non-irradiated versions, but how much more is unclear.

The biggest economic challenge lies in projecting market demand for irradiated fruits and vegetables. Demand for other irradiated foods (such as beef and poultry, for example) has not grown rapidly, and most irradiated foods still comprise only a very small fraction of their markets. Without strong market demand, it is unlikely that investors would choose to absorb the large up-front (research) costs needed to support specific new applications of food irradiation. It is unclear, therefore, whether economic conditions would favor the growth of a market for irradiated fruits and vegetables, even if this irradiation use were authorized by the FDA. Even if irradiated fruits and vegetables do eventually appear on the market, the vast majority of produce will remain non-irradiated.

Will consumers accept irradiated produce?

Some will and some won't. Some people will be attracted by the perception that irradiated produce is safer, while others will find the unanswered safety questions, or the thought that irradiation might come to be used as a back-stop for inadequately safe production practices, troubling, and choose not to buy irradiated fruits and vegetables. Some might choose organic produce because they know it is not irradiated, while others might avoid organic for exactly the same reason. In the end, the acceptability of irradiated produce will depend primarily on its sensory quality (it will need to be comparable to non-irradiated produce), and on the perception that it really is safer, i.e., delivers added value, especially if it costs more than non-irradiated produce. If these conditions are met there is no reason why most consumers would not be willing to try irradiated fruits and vegetables.

Conclusion

Food irradiation seems to have some potential to be a useful tool for managing problems of pathogens on fresh produce. But the research needed to support these applications is a relatively new and still small field. A great deal more research is needed to answer basic scientific questions and work out practical details. The FDA has not approved irradiation of fresh produce for pathogen control, largely because some of the scientific data needed to support a regulatory decision do not exist yet. Given the complexity of the problems, the amount of research that still needs to be done and the lack of market demand to drive that research, it seems unlikely that irradiation of fresh produce will become a practical reality for several years, perhaps even longer.

The critical questions—whether irradiation can make pathogen-contaminated fruits and vegetables acceptably safe without unacceptably altering their sensory quality, whether commercial-scale produce irradiation is technically and economically feasible—cannot be adequately answered at present. It is not clear yet whether fresh fruits and vegetables irradiated for safety reasons will eventually reach the market. Even if they do, the vast majority of produce will remain non-irradiated for the foreseeable future.

Critical Scientific Issues

Pathogens in produce: Growing awareness of the problem

Food-borne illness from human disease organisms that contaminate meats and poultry, in particular, has long been a high-priority food safety issue. Awareness has grown during the past 10 to 15 years that fresh produce and minimally processed products such as fruit juices and pre-cut salads can be significant sources of food-borne illness (Sivapalasingam et al. 2004; see also Box 1).

A major outbreak of illnesses caused by *E. coli O157:H7* in the fall of 2006 was linked to fresh spinach (FDA 2006a), and another *E. coli* outbreak two months later was traced to lettuce used at Taco Bell restaurants (FDA 2006b). These and other incidents, such as for example several involving tomatoes contaminated with *Salmonella* (CDC 2005a, 2006), have heightened concern about produce-borne food poisoning among the food industries, safety regulators and consumers.

E. coli O157:H7, a particularly virulent strain of fecal bacteria that lives in the intestines of cattle and other ruminants, is the pathogen behind several recent outbreaks (see figures in Box 1). Trends toward centralization and intensification of both animal production and fruit and vegetable processing appear to have increased the risk that *E. coli O157:H7* will contaminate produce (Organic Center 2006). More effective counter-measures are clearly needed to better manage this risk.

In this climate of urgency about improving produce safety, a long-available technology, food irradiation, has been proposed by some advocates as an important solution (see, for example, WSJ 2006). At least in theory, food irradiation, which is proven effective at killing bacteria in certain other foods, could help mitigate pathogen hazards on produce. However, irradiation of fresh produce to kill pathogens has not been authorized by the US FDA, nor is it clear that it is technically and economically feasible for many specific produce-pathogen problems. This report examines some of the scientific questions and practical considerations that must be addressed and resolved to determine how useful food irradiation might be in the future for enhancing produce safety.

What is food irradiation?

Food irradiation involves exposing foods to large doses of ionizing radiation, in order to kill or deactivate bacteria, molds, insects or other food-borne organisms, and to inhibit plant growth and maturation. Irradiation was first developed in the 1940s and has been used, in limited ways, in many countries, for several decades. Irradiation preserves food quality and extends shelf life in two ways: It kills spoilage organisms, and it slows plant ripening. Certain specialty foods—for example, meals taken into space by astronauts, or hospital foods for immuno-compromised patients, where food sterility is desired—are sometimes irradiated. Many spices are irradiated (to kill insects, molds and bacteria) and some foods traded internationally are irradiated, to keep exotic pests from spreading.

Box 1:

Food-Borne Illness: A Pressing Problem

With each flood of media stories about the latest food-poisoning outbreak, the statistics grow more familiar: 76 million Americans get sick every year from disease-causing organisms in their food. 325,000 are sick enough to be hospitalized, and 5,000 of them die. Young children, the elderly, and people with compromised immune systems are at the highest risk, but food poisoning can affect anyone.

Over 250 different food-borne illnesses are recognized, but the most prevalent bacterial pathogen problems in foods are *Campylobacter*, *Salmonella* and *E. coli O157:H7* (CDC 2005c).

The CDC has compiled data on the foods associated with "outbreaks" (an outbreak is a cluster of food-borne illnesses traced back to a common cause). For the years 1993-1997 (the latest period covered by detailed analysis), there were 967 outbreaks associated with known food sources (CDC 2000). (The causes of two-thirds of the food-borne illnesses reported to the CDC are never conclusively determined.) Fish and seafood accounted for the most outbreaks, 187 (19 percent).

Fresh produce, such as fruits and vegetables, salads, and mushrooms, was linked to 97 outbreaks (10 percent), ranking it second behind seafood and well ahead of both beef (7 percent) and poultry (5 percent). Produce was associated with two of 16 deaths in those outbreaks with known causes. Only about 20 produce-related food poisoning outbreaks were reported in the 1970s, but nearly 100 occurred in the 1990s (Sivapalasingam et al. 2004). Although part of the increase could be due to improved monitoring and reporting systems, the problem of contaminated produce is clearly getting worse.

Another CDC analysis showed that the bacteria most often associated with produce-related outbreaks from 1998 through 2002 were *Salmonella* (26 percent) and *E. coli* (8 percent) (Tauxe 2005). Based on outbreak data over the past 15 years or so, ground beef has been the most likely source of exposure to *E. coli O157:H7* by a wide margin (see Figure). But the occurrence of this pathogen in produce is a growing concern (Organic Center 2006).

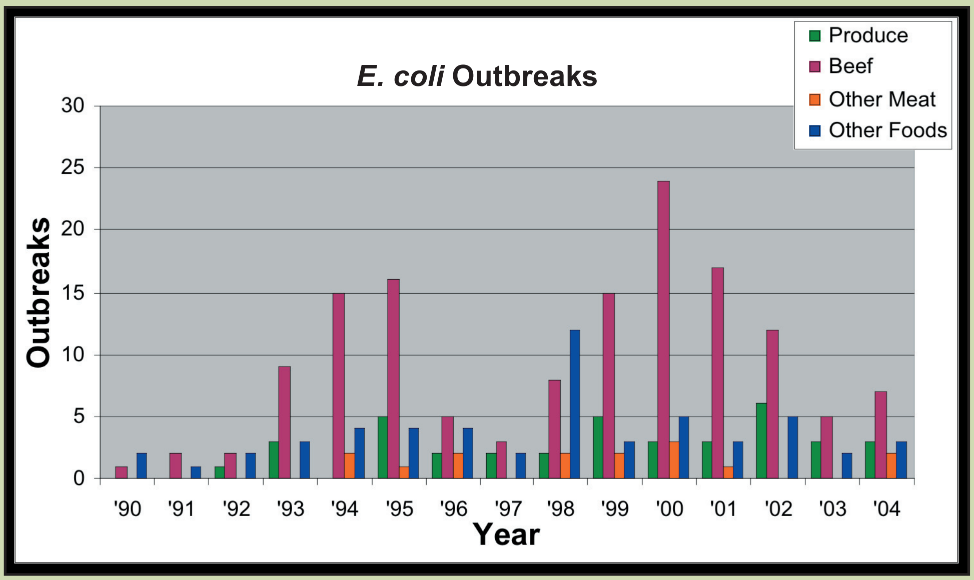
Among 249 produce-associated outbreaks reported to CDC between 1998 and 2002 that were linked to single foods, the most frequent vehicles, in descending order, were lettuce, sprouts, fruit juices, melons, tomatoes and berries (Tauxe 2005).

The figure on page 7 tracks *E. coli* outbreaks over recent years and shows the relative frequency with which foods of different types were associated with the outbreaks in each year.

Given the myriad ways pathogens can get into foods, preventing food poisoning is a huge and complex challenge. Even if foods are clean and safe when purchased, for instance, they can be contaminated during preparation or storage. CDC estimates that 20 percent of food poisoning outbreaks are caused by careless handling and lack of proper refrigeration in restaurants, cafeterias and other food-serving establishments.

In the quest for solutions to this knotty problem, various experts have offered scenarios about potential benefits if food irradiation were widely used. CDC's Robert Tauxe, for example, estimated that if half of all ground beef, poultry, pork and processed meat were irradiated, 350 deaths/year could be prevented (Consumer Reports 2003).

However, even if the uses of food irradiation could be expanded to that degree (more than a ten-fold increase from current levels), 350 deaths is only 7 percent of the estimated toll from food-borne illness each year. Irradiating produce, if it becomes available, would be even more limited in the food safety benefits it could reasonably be expected to deliver, even under optimistic assumptions about how widely it would be used. Clearly, multiple strategies and combinations of risk-reducing measures are needed, across the entire farm-to-table food production chain, to combat produce-borne pathogens and make fruits and vegetables as safe as they can be.



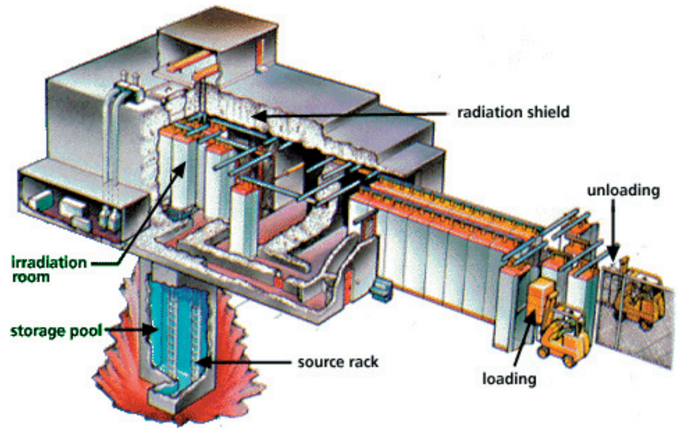
US outbreaks of food-borne illness due to *E. coli O157:H7*, 1990 to 2004, with associated food categories.

SOURCE: OUTBREAK ALERT! A database maintained by the Center for Science in the Public Interest (CSPI). (June 2006).

Food irradiation can also be used to kill disease-causing bacteria and make foods safer. As such, irradiation is a potentially useful tool to improve the microbiological safety of treated foods. It is not a panacea, and is generally considered to be simply an additional safety measure, i.e., a supplement to, not a substitute for, Good Manufacturing Practices and Good Agricultural Practices (GMP and GAP) that must be employed "upstream" in the production process, to keep microbial hazards out of foods as much as possible.

How does irradiation work?

Food irradiation can use any of three types of ionizing radiation: x-rays, gamma radiation or electron-beams. (For a more detailed description of the differences between the three types and the advantages and disadvantages of each type of irradiation, see Niemira and Sommers 2006). Irradiation takes place in a heavily shielded chamber (see Figure); as food passes through on a conveyor belt, it is typically irradiated from different angles, to ensure that the radiation fully permeates the target food.



Courtesy of Isomedix, Inc.

When ionizing radiation passes through biological tissues such as foods, some of the energy of the radiation is absorbed by molecules in the food. The amount of radiation energy absorbed by the food is called the irradiation "dose" (see Box 2). Absorbed radiation energy "excites" electrons (i.e., accelerates their revolution in their atomic orbits) in food molecules, until some of those excited electrons fly out of their orbits,

Box 2:

Understanding Irradiation Doses

The radiation doses used to treat food are expressed in units that indicate the amount of energy absorbed by the irradiated food. The standard unit of irradiation dosage is the grey (Gy); 1 Gy = 1 joule/kg. A joule is a basic unit of energy, the amount needed to heat one gram of dry air by one degree Celsius; the kg in this case is a kilogram of food. The doses used in food irradiation are ordinarily expressed in kilogreys (kGy), i.e. 1000 Gy.

A kGy is a very large dose of radiation. For comparison, the average medical chest x-ray delivers a dose equivalent to 0.06 milligreys (0.00006 Gy), while a mammogram exposes the patient to about 0.45 mGy. The average American is exposed to about 3.6 mGy of radiation from natural and technological sources per year. Occupational health limits permit workers to be exposed to up to an additional 0.5 mGy in a single year. Exposure to 1 Gy increases lifetime cancer risk by 5 in 100, and a dose of 10 Gy will kill a human adult within days or weeks of exposure (CCOHS 1999).

When foods are irradiated, the radiation dose used can range from about 0.1 to 30 kGy. For fresh produce, doses around 1 kGy are typical. 1 kGy is the equivalent of roughly 17 million chest x-rays, and about 100 times greater than a lethal dose.

These doses unquestionably are high enough to kill the vast majority of bacteria (at least, those that don't form spores) in irradiated foods. The large amount of energy involved produces other effects as well, for example on the sensory quality of the food. These side-effects of irradiation require careful evaluation when assessing the pros and cons of specific proposed food irradiation applications.

creating charged particles. This "ionizing" effect splits molecules. The primary mechanism by which food irradiation kills bacteria is by splitting water molecules into hydrogen (H^+), hydroxyl (OH^-) and oxygen (O^{-2}) radicals. Those radicals react with and destroy or deactivate bacterial components such as DNA, proteins and cell membranes (Niemira and Sommers 2006). Radiation can also damage or break large molecules such as DNA and enzymes. These effects prevent bacteria from reproducing and suppress the pathogen population's growth, effectively "killing" germs in the food.The doses of radiation used to treat foods in this manner are very large (see Box 2). Such large doses are needed to ensure killing the vast majority of individual bacterial cells on an irradiated food.

What foods are now permitted to be irradiated?

Since food irradiation acts as a food preservative and can change chemical, physical and sensory properties of foods, it is regulated as a "food additive" by the US Food and Drug Administration. FDA regulates the foods that may be irradiated, the purposes for which they may be irradiated, and the doses that may be used in each case. Specific irradiation uses must be approved by the FDA as safe and effective before they are commercially applied.

The FDA has approved irradiation of the following foods, for the purposes specified in each case (FMI 2000):

- Refrigerated or frozen uncooked (red) meat, including ground beef, to eliminate potential food-borne pathogens, such as *E. coli O157:H7* and *Salmonella*, and to extend shelf life (1999).
- Poultry feed, to eliminate *Salmonella* (1995).
- Fresh or frozen packaged poultry, to control *Salmonella*, *Camplylobacter* and other illness-causing bacteria (1990, 1992).
- Fresh fruits, vegetables and grains, to control insects and inhibit growth, ripening and sprouting (1986).
- Pork, to control the parasite *Trichinella spiralis*, which causes trichinosis (1985).
- Herbs, spices and vegetable seasonings, to kill insects and control microorganisms (1983-1986).
- Dry or dehydrated enzyme preparations, to control insects and microorganisms (1985).
- White potatoes, to inhibit sprout development (1964).
- Wheat and wheat flour, to control insects (1963).

While irradiation of fresh fruits and vegetables at doses up to 1 kGy has been permitted for 20 years to kill insects and extend shelf life, irradiating produce to kill pathogens has not been approved, and would require a new authorization by the FDA.

In 1999, a food industry coalition led by the National Food Processors Association (now known as the Food Producers Association) submitted a petition to FDA, seeking approval to irradiate a broad range of ready-to-eat foods. Their primary focus was to gain approval for irradiation of lunchmeats, to control *Listeria monocytogenes* and other pathogens, but the petition also included fruits and vegetables, seeds, sprouts and juices.

The number and variety of foods and pathogens included and thus the complexity of the associated effectiveness and safety issues raised by this wide-ranging petition gave FDA a difficult evaluation task, which the agency has not yet completed. The petition is still technically pending and under review. However, produce industry sources say that lack of regulatory approval is not the major obstacle to irradiation of fresh produce. The more serious obstacles are unanswered questions about the technical and economic feasibility of irradiating products like lettuce and spinach to kill pathogens (Stenzel 2007).

By law, most irradiated foods (spices are exempt) must carry the phrase “treated with radiation” or some comparable wording on their label, with a visual symbol called the “radura” (see Figure).

Food irradiation is also addressed in the national organic food standards, adopted by the US Department of Agriculture. Organic foods may not be irradiated.

“Radura”

Despite relatively long-standing FDA approval for the uses listed above, irradiated foods are not widely available in the US. Irradiated ground beef has gained a small footing in the past few years, and irradiated poultry is available in some supermarkets. Irradiated strawberries, mushrooms, grapefruit and other items have been sold in some parts of the country, off and on over the last 20 years, and irradiated mangoes, papayas and apples have been test-marketed in a few states (FMI 2000). Overall, irradiated foods make up a very small portion of the national food supply.

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Why is irradiated food not more widely available?

Food irradiation has historically been controversial in the US. While many health and food safety authorities have endorsed it as a useful and acceptably safe technology, some consumer and public-interest organizations (e.g., Public Citizen, the National Organic Consumers Association) have opposed food irradiation for a variety of reasons.

Debate over food irradiation has been politicized and polarized, and advocates on both sides tend to use strong rhetoric. Some of its proponents see irradiation as a life-saving technology that has been underutilized because of scare campaigns by its opponents. A recent editorial in the Wall Street Journal (WSJ 2006) suggested that irradiation could have prevented the recent *E. coli* outbreaks, and blamed “political pressure, media scare tactics and bureaucratic and industry timidity” for failure to use irradiation more widely.

But reality is more complicated. Food irradiation is a potentially useful tool in the battle for a safer food supply, but it is an expensive “technical fix” that requires both a major up-front investment and intensive ongoing management. Many other approaches also can be used (and must be used) to enhance food safety at multiple steps between the farm and the consumer. Determining whether irradiation is effective and safe enough, whether a specific application is cost-effective, and whether it might be the best risk management option for a specific problem, requires considerable scientific evidence on that particular food safety issue and a detailed review of the pros and cons of the specific proposed irradiation application.

Simply stated, there is not yet a large market demand for irradiated foods in the US. In the absence of driving market forces, relatively little research has been done to answer questions about the usefulness and feasibility of irradiation applications to specific new food safety problems. In a kind of “vicious circle,” the lack of adequate scientific data on new irradiation applications makes it harder for the FDA to answer questions it needs to answer before approving such new uses. Without FDA approval, novel irradiated foods cannot be marketed, and demand for them is thus likely to remain weak.

In a nutshell, this is the situation facing proposals to irradiate fresh produce for control of pathogens like *E. coli O157:H7*. While irradiation might potentially be a useful additional tool for this purpose, many key questions cannot be effectively answered with available scientific evidence, and progress toward resolving the questions will probably be slow.

The remainder of this report examines some of those critical questions, and summarizes what is known and not known on each topic.

Can irradiation enhance product safety?

Potential advantages of irradiation

In theory, irradiation certainly could make some produce safer. Scientists at the Eastern Regional Research Center of the US department of Agriculture (USDA ERRC) have been investigating uses of food irradiation to control several different kinds of bacteria in a variety of fresh fruits and vegetables. In a review of that research, the ERRC's Brendan Niemira (2003) mentioned non-thermally-pasteurized (NTP) juices, fresh sprouts, pre-cut vegetables, prepared salad mixes, fruit salads and other minimally processed vegetable products as good candidates for irradiation to enhance their safety.

Irradiation has potential appeal especially for products that are not intended to be cooked and are eaten with minimal further processing, such as salads. Irradiation might eliminate pathogens without affecting the sensory quality of NTP fresh fruit juices, whose complex aromatic flavors—their main attraction for consumers and the basis for their premium prices—are destroyed or severely diminished by heat pasteurization.

Irradiation also seems attractive because many currently-used treatments for fresh fruits and vegetables (such as washing, chlorination, warm-water dips) are not particularly effective, reducing bacterial populations by only 90 to 99 percent or so. While bacterial reduction of that magnitude is useful for reducing spoilage and extending shelf-life, when pathogens like *E. coli O157:H7* may be present, more effective antimicrobial treatments are required (IAEA 2006).

Fresh produce could be irradiated after it is packaged, as a final step; this approach would have the additional advantage of avoiding possible re-contamination in processing. Also, irradiation to kill pathogens should kill most spoilage organisms, extending shelf life and preserving appearance and sensory quality. These perceived advantages, combined with recent awareness of the prevalence of *E. coli* and other pathogens in fresh vegetables, have spurred growing interest in applications of food irradiation to this particular set of food safety problems. But studies investigating irradiation of various fresh fruit and vegetable products suggest that moving from theory to practical applications will be neither a rapid nor a simple process.

While irradiation certainly can kill pathogens, how effectively and reliably it does so is determined by multiple factors. No single approach fits all foods; irradiation procedures need to be carefully tailored to fit specific food/pathogen combinations. Irradiation can adversely affect the physical appearance and sensory quality of treated foods; vegetable products are generally more sensitive to these effects than meats are, for example, and tolerable irradiation dosages need to be determined for specific candidate foods. Finally, since irradiation can chemically change treated foods, each specific irradiated food and food category needs careful evaluation to ensure that it is safe to eat.

What determines how well irradiation kills pathogens on produce?

Most research on irradiated produce carried out to date has been concerned with control of spoilage organisms, rather than pathogenic bacteria. Those studies provide useful data, for example, on radiation doses that can be tolerated by various fresh fruit and vegetable products, without significant damage to sensory quality. But relatively few studies have examined irradiation to control specific food poisoning organisms in specific fruits and vegetable foods. The existing studies suggest a number of particular questions on which more research is clearly needed.

The effectiveness of irradiation is likely to vary with the type of radiation used, e.g., x-rays, gamma radiation or electron beam, but few studies have compared the effectiveness of different radiation types for specific pathogens on specific foods (Niemira 2003).

The sensitivity of microbes to irradiation also varies with the type and strain of organism involved. *E. coli* bacteria appear to be killed by lower radiation doses than *Salmonella* or *Listeria* are, but different strains of any particular pathogen may be more or less resistant to irradiation than the species is on average (Buchanan et al. 1998). Molds and viruses are generally harder to kill with irradiation than bacteria are (Niemira and Fan 2006).

The effectiveness of antimicrobial measures also depends on the food matrix in which the bacteria of interest are living. There is a "biofilm" on the surface of fruits and vegetables, a complex community of many microbial species, bound to the plant surface. Bacteria in this matrix are largely protected from washing off and from anti-microbial agents such as chlorine, ozone or hydrogen peroxide (Stewart et al. 2004).

The irregular surfaces of fruits and vegetables also contain "microniches" that can shield bacteria from chemical and physical antimicrobial treatments, such as chlorine washing or dipping in mildly heated water (Niemira 2003). Bacteria can get inside tissues of leafy vegetables, through natural openings (e.g., stomata) or through breaks in the leaf surface caused by insect or pathogen damage or mechanical breakage in harvesting, processing and handling (Takeuchi and Frank 2000, Solomon et al. 2002). Bacteria can sometimes also enter roots along with water taken up from the soil, then be translocated within the plant, reaching edible tissues.

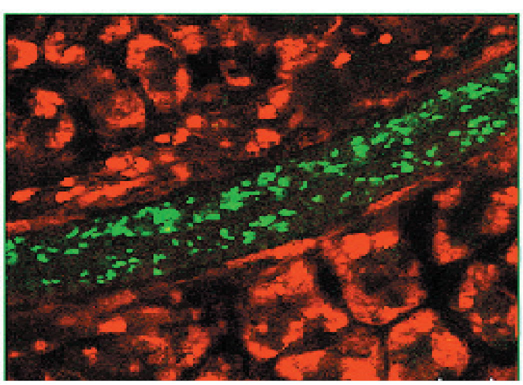

Photo by Marian Wachtel.

E. coli (fluorescent green) in xylem of cut leaf lettuce.

Irradiation can kill bacteria embedded in protective biofilms, or living within the contours or beneath the surfaces of fruits and vegetables, better than surface treatments can, due to its penetrating nature. Irradiation thus is potentially more effective than washing or other surface treatments against spoilage organisms and pathogens (Niemira and Fan 2006).

Specific physical and chemical characteristics of particular foods also influence effects of irradiation on bacteria in those foods. For example, the pulp content and turbidity of juice affect the radiation dose required to kill *E. coli* (Buchanan et al. 1998). Antioxidants in vegetables can influence the effectiveness of irradiation (Niemira 2003); antioxidants tend to scavenge free radicals produced by radiation, reducing its anti-microbial effects.

A single food variety may be marketed in several different forms. For example, tomatoes may be sold whole, sliced, diced (in salads); iceberg lettuce may be sold as heads, single leaves (on salad platters), cut into pieces (in salads), or shredded (shredded lettuce was associated with the recent *E. coli* outbreak at Taco Bell restaurants, for instance). Effects of irradiation may differ for different forms of the same foods, and effectiveness needs to be evaluated not just for the food in general, but for all the permutations of that produce item that appear in widely-consumed products.

Irradiation kills most, but not all, members of a bacterial population in an irradiated food. Effectiveness is generally expressed in terms of "log" reductions, i.e., numbers of powers of ten by which the population is reduced (see Box 3). A 4-log reduction, for example, means a 99.99 percent (10,000-fold) reduction in the bacterial population.

Expert authorities generally recommend that foods prone to contamination by pathogens like *E. coli O157:H7* or *Salmonella* should be treated in some fashion (e.g., pasteurized) that achieves a 5-log reduction in bacterial loading (Buchanan et al. 1998; Niemira 2003). Experiments with irradiation of vegetables have generally shown that doses large enough to produce a 5-log reduction in bacteria often also produce unacceptable changes in the quality and sensory appeal of the foods (see section below). Radiation doses that produce can tolerate without significant loss of food quality usually have less effect on bacterial loads, in the range of 2 to 4 logs (see next section). Whatever the log reduction achieved by irradiation, some bacteria will survive. When conditions favor bacterial growth, the survivors can

Box 3:

The more logs the better

Bacteria are very small, but their populations are enormous, in numerical terms. 1,000 to 1,000,000 bacteria per gram live on most fruits and vegetables (Niemira 2003). An average 100-gram (3.5 ounce) apple can carry 100,000 to 100,000,000 bacteria.

Most bacteria are harmless to humans, although some can spoil foods. But if produce is contaminated with disease-causing bacteria such as *E. coli O157:H7*, good hygiene must be practiced to ensure that those pathogen populations do not grow to harmful levels. Occasionally, when hygienic measures are insufficient, produce may contain pathogen populations large enough to pose a clear hazard to public health.

Scientists describe bacterial populations in terms of "logs," or powers of ten. A 6-log population is a million bacteria, for example. Reductions in populations achieved by anti-bacterial treatments are also measured in logs. For instance, if chlorine washing reduces bacteria on lettuce by 99 percent, that is a 2-log reduction.

The "infectious dose"—the number of bacteria required to cause illness in a person who eats a contaminated food—can be as low as 10 to 100 bacteria per gram of food, for *E. coli* and other critical food-borne pathogens. Highly effective hygiene measures are clearly needed to keep disease-causing bacteria like *E. coli O157:H7* at safe levels.

An expert committee on food safety has recommended that fruit juices, for example, should be heat-pasteurized or treated in some other way that achieves at least a 5-log reduction in bacterial loading (NACMCF 1997). If a food starts out with 100,000 *E. coli* per gram, safety treatments need to reduce the pathogen population by at least 5 logs to make the food safe. A 5-log reduction from that starting point would leave 1 bacterial cell on average per gram of the treated food. Conversely, a treatment that could achieve only a 2-log reduction would achieve the "safe" level of one viable cell per gram only if the initial pathogen population were 100/gram or less.

The irradiation doses used to treat meat and poultry typically achieve reductions of 4 to 6 logs. But fresh fruits and vegetables are more easily damaged by irradiation, and have to be treated with lower doses. Irradiation of produce generally reduces bacterial loads only 2 to 4 logs (Niemira 2003).

Is that enough to make irradiated produce safe? This critical question is examined in detail in the sections of this report that follow.

reproduce and "re-grow" a bacterial population in the food. The extent of re-growth depends on the length of time between irradiation and consumption, temperatures at which foods are stored and on other factors, such as whether the food is damaged (as it may be by irradiation), and on competition between pathogens and non-pathogenic bacteria present on foods for nutrients and other resources (Niemira 2003).

As the statistics reviewed in Box 1 show, foods can become contaminated with bacteria during post-market handling, storage and food preparation, and bacteria introduced at these points can also grow to harmful levels, if conditions permit. This possibility is as real for irradiated produce as it is for any other produce.

Some of the vegetable products, fruit juices, salads and similar foods now considered to be candidates for irradiation may be stored for up to several weeks between processing and consumption. The potential for bacterial re-growth after irradiation therefore is one critical aspect of an evaluation of irradiation's effectiveness at pathogen control in these products. If irradiation is used, additional steps designed to prevent recontamination and to limit the growth of surviving or reintroduced bacteria in the post-irradiation period are likely to be essential parts of the risk management strategy.

How well does irradiation control bacteria on produce?

Within the general context described in the preceding section, a relatively small body of research, much of it carried out by the USDA ERRC, has examined the effectiveness of irradiation treatment to control pathogens in fresh fruits and vegetables and related food products. Some additional studies have tested irradiation effects on total bacteria counts (sometimes expressed as total aerobic count, an index of bacterial varieties that thrive in the presence of oxygen) found on fresh fruits and vegetables. Both types of data can be used to assess the potential effectiveness of irradiating specific foods of interest here.

Niemira et al. (2002) tested the effects of irradiation on *E. coli O157:H7* on four types of lettuce (Boston, iceberg, romaine and endive). Subtle differences between lettuce types significantly affected the sensitivity of the pathogen to radiation.

In a study using pre-cut bell peppers, Farkas et al. (1997) found that irradiation at 1 kGy reduced total plate count and *Listeria monocytogenes* by ~ 4 logs. Bacterial regrowth was minimal on samples stored at refrigeration temperature (5°C, 40°F); however, on peppers stored at 10 or 15°C (50 or 60°F), i.e., not refrigerated, pathogen populations returned to pre-irradiation levels within four days.

Endive inoculated with *Listeria monocytogenes* was irradiated at 0.42 kGy (calibrated to achieve a 2-log reduction) and at 0.84 kGy (to achieve a 4-log reduction). At the lower dose, bacterial populations re-grew to pre-treatment levels during 19 days of refrigerated storage, while re-growth was minimal at the higher dose (Niemira et al. 2003).

Prakash et al. (2000) irradiated diced celery at 0.5 and 1.0 kGy and found greater than a 5-log reduction of both *E. coli* and *L. monocytogenes*. In the same study, irradiation was more effective than conventional treatments (acidification, blanching and chlorination) at suppressing bacterial re-growth during 22 days of post-treatment storage.

Rajkowski and Thayer (2000) irradiated several kinds of salad sprouts inoculated with *E. coli O157:H7* and *Salmonella* and determined the radiation doses required to achieve a 1-log (90 percent) reduction of pathogen loads. The doses were 0.34, 0.27 and 0.26 kGy for *E. coli* on radish, alfalfa and broccoli sprouts, respectively, and from 0.46 to 0.54 kGy for *Salmonella* on radish sprouts.

Researchers at the USDA ERRC have reported that a combination of low-dose irradiation (0.5 or 1.0 kGy), a warm-water dip, and modified-atmosphere packaging (MAP) reduced bacterial loads in lettuce more effectively than irradiation alone, without significant loss of sensory quality (Fan et al. 2003b). Irradiation at 0.3 and 0.6 kGy combined with MAP reduced *L. monocytogenes* on endive by 2.5 to 3 logs (Niemira et al. 2005); the pathogen populations re-grew to pre-treatment levels in samples stored in ordinary air, but MAP suppressed re-growth. Irradiation at doses of just 0.19 and 0.35 kGy combined with MAP reduced aerobic counts by about 3 logs on iceberg lettuce and about 1.5 logs on romaine lettuce, respectively, and effects persisted during storage (Niemira 2003).

Kim et al. (2005) irradiated fresh-cut green onions and found that doses of 1.0 to 1.5 kGy reduced total aerobic count by about 3 logs, but with this particular food, a warm water dip had no additional anti-bacterial benefits.

Buchanan et al. (1998) inoculated apple juices with different strains of *E. coli O157:H7* and irradiated the juices to determine doses needed to control the pathogen. Differences in the effectiveness of irradiation depended on the strain of bacteria and the amounts of suspended solids in the juices. The authors calculated that an irradiation dose of 1.8 kGy should achieve the desirable 5-log reduction in *E. coli* for any of the tested juices.

Overall, research on the effectiveness of irradiation for controlling pathogens in fresh vegetables and fruit juices is a relatively new field, and very few definitive answers exist. The available research suggests that irradiation clearly has significant potential to be a useful safety measure for these food categories. However, more research is also clearly needed to identify and define appropriate, precise ways to apply the tool.

Niemira (2003) emphasizes, for example, that the effects of irradiation depend heavily on the type of food. For example, results varied among four different kinds of lettuce in one study. As Niemira points out, even for a single food type, varieties and cultivars grown commercially can differ widely from year to year and region to region. Further research will be required to determine how well and at what dosages irradiation may be effective for controlling specific disease organisms on specific produce varieties.

Because most vegetables are damaged by irradiation at doses that would reduce pathogen populations by the desired 5 logs, lower radiation doses, with lower kill rates, generally are used for these foods. Some recent studies suggest that low-dose irradiation, combined with other good manufacturing practices and preservation techniques, effectively controls certain pathogens. However, more research is needed to determine what combinations of measures are effective against what specific pathogens in what specific foods.

A critical question is whether the 2- to 4-log reductions in pathogen populations likely to be attained with low irradiation doses provide sufficient food safety. The long intervals that can pass between processing and consumption of vegetable products heighten the concern about bacterial re-growth following food safety treatments, including irradiation. Further investigation is needed of the extent to which pathogen re-growth can occur on irradiated vegetable products under a variety of conditions. In this context, Niemira and Fan (2006) point out that irradiation-induced changes in microbial communities living on produce, which could indirectly affect pathogen re-growth, e.g. by reducing competition, also need to be evaluated.

A final critical research need related to effectiveness is to go beyond small-scale, well-controlled laboratory experiments such as those by the ERRC and begin collecting data on the effectiveness of irradiating produce on a commercial scale. Whether doses that are effective in laboratory studies reviewed here will work as well in commercial irradiation facilities could be affected by several factors.

For example, in commercial production, a treatment process is typically calibrated at the start, then a large volume of food is run through. It is impossible to check every package after irradiation to determine whether each part of each package absorbed the intended dose and the treatment had the desired effects. Quality-control procedures would need to be developed (statistical sampling, for example) to support assumptions that the process was working as intended.

These considerations may be particularly relevant when fresh fruits and vegetables are being irradiated. Given seasonal harvests and the premium placed on product freshness, crops would probably pass through irradiation facilities in high-volume, short-duration bursts. Economic necessity would require rapid, large-batch processing, and under those conditions, effective quality assurance measures could be especially critical to ensure that contaminated produce did not slip through the irradiation net. Research to determine how feasible this is on commercial scales probably will not be done unless entrepreneurs are actually preparing to market irradiated produce.

What other effects does irradiation have on fruits and vegetables?

Does irradiation affect nutritional quality?

In theory, irradiation could adversely affect the nutritional quality of foods. High-energy ionizing radiation that breaks molecules might destroy vitamins in fruits and vegetables, for instance. Irradiation of citrus fruits and juices has been shown to oxidize a portion of the ascorbic acid (Vitamin C); but according to Niemira et al. (2001), since the oxidized and the non-oxidized forms of the molecule are both biologically active, the nutritional impacts of this effect are likely to be minimal. Fan (2005a) found that three varieties of irradiated lettuce contained higher levels of antioxidants and phenols (desirable nutrients) than controls; i.e., irradiation in this case improved the nutritional quality of the food.

How does irradiation affect the sensory quality of produce?

As noted previously, irradiation doses commonly used on meats, poultry and other foods can degrade the appearance and sensory quality of many fresh fruits and vegetables. This sensitivity to irradiation damage led most researchers to assume for many years that fresh produce foods were not suitable for irradiation. More recently, however, the possibility of using lower radiation doses to control pathogens (and spoilage bacteria) while preserving or even enhancing food quality of fruits and vegetables has been a focus of research.

A great many studies have documented the adverse effects of irradiation on the sensory quality of foods. While most investigators have judged the sensory quality of irradiated foods to be “acceptable,” there is substantial evidence that at least some subtle off-flavors and odors are produced in most irradiated foods. For example, a trained sensory panel described a “singed hair” note in irradiated chicken and ground beef (Consumer Reports 2003). An off-flavor in irradiated turkey is described as “wet dog,” among other terms (Fan et al. 2004). Off-odors produced when eggs, milk and dairy products are irradiated are so strong and unpleasant that these foods are considered not suitable for irradiation (FMI 2000).

Numerous studies have explored the effects of irradiation on the quality of fresh fruits and vegetables. The common purpose of most of this research has been to determine a dose of irradiation high enough to effectively reduce bacterial loads, but low enough to avoid unacceptable effects on food quality. Results suggest that the dosage range where positive and negative effects are both within acceptable limits is rather narrow for most tested fruits and vegetables.

Fan et al. (2003a) and Kim et al (2005) irradiated sliced green onions at doses ranging from 0.5 to 3 kGy. Doses greater than 1.5 kGy caused loss of aroma and visual quality, and onions treated at those doses showed signs of cellular damage (electrolyte leakage). But lower doses of radiation (0.5, 1.0 and 1.5 kGy) reduced bacterial loads while color, texture and aroma were preserved, and decay and development of off-odors during 14 days of storage were reduced.

Fan and Sokorai (2005) irradiated 13 types of fresh-cut vegetables at dosages ranging from 0.5 to 3 kGy and measured tissue damage by electrolyte leakage. Damage increased linearly with dosage for all 13 vegetables, but sensitivity to radiation varied widely from food to food. Green onions, celery, red lettuce and carrots were the most sensitive, while broccoli, endive and red cabbage were the most resistant vegetables tested. Spinach, cilantro, romaine lettuce, iceberg lettuce, parsley and green leaf lettuce were intermediate in sensitivity. Radiation doses that increased electrolyte leakage by 50 percent over non-irradiated controls ranged from about 0.6 to 1.4 kGy.

Fan (2005a), in the study cited above that found irradiation improved the nutrient content of lettuce, observed that the irradiated lettuce showed greater browning (loss of visual appeal) than controls, possibly as an effect of the increased phenolic content. The same investigators (Fan et al. 2003b) reported that irradiation doses greater than 1 kGy caused softening (loss of crispness), browning and decreased vitamin C content in lettuce, while earlier work had shown that irradiation at 2 kGy wilted lettuce. But they also found that when lettuce irradiated at 0.5 and 1.0 kGy was dipped in water heated to 47°C (117°F), the combination of treatments reduced bacterial loads by about 3 logs without significant effects on sensory quality or vitamin C content.

Celery irradiated at 1 kGy was evaluated by a sensory panel and other measurements and was judged superior in sensory quality to celery preserved by other methods (blanching, acidification and chlorination) and to untreated celery (Prakash et al. 2000).

Irradiation breaks down pectin, a binding component in plant tissues, and this results in softening of some irradiated fruits and vegetables. Strawberries, cucumbers (pickles) and potatoes exhibit softened texture following irradiation (Niemira 2003). Fresh-cut apples irradiated at doses greater than 0.34 kGy and diced tomatoes irradiated at 1.25 kGy lost firmness (Niemira and Fan 2006). Grapefruit irradiated at 0.6 kGy showed softened pulp, pitted skin and loss of juice quality (Niemira 2003).

Fruit juices of several types were irradiated at doses up to 5 kGy without adverse effects on sensory quality as measured by a taste panel (Nemira 2003). Irradiation at 5 kGy has been reported to degrade the flavor of grape juice, and orange juice and apple juice lost substantial sensory quality when irradiated at high doses (3 to 10 kGy). But doses of 2.5 kGy or less had no significant adverse effects on sensory quality of irradiated apple juice or orange juice (Niemira 2003.) At higher doses, addition of sorbic acid may prevent the development of off-flavors in juices during irradiation (Thakur and Singh 1993).

As in studies of irradiation's effectiveness, the specific types and varieties of the foods involved are critical variables. Sensory effects of irradiation on fruits, vegetables and juices are likely to be highly variety-specific (Niemira 2003). Given the complexity of sensory quality determinants and the large number and changing nature of crop varieties coming to market, determining the sensory effects of irradiation on fruit and vegetable products poses a complex challenge for the food science research community.

Finding the right balance

Effects of irradiation on sensory quality of fruits and vegetables are a two-edged sword. By killing bacteria it can help retard spoilage, which preserves appearance and sensory quality and extends shelf life. But irradiation also damages plant cells, which can speed quality deterioration and support bacterial re-growth. Irradiation also may cause direct chemical changes that could affect sensory qualities of produce.

An "optimal" dose of irradiation would have benefits large enough to improve safety or shelf life significantly, without adverse sensory effects large enough to be unacceptable to consumers and producers. Such optimal doses may not exist for all foods. Finding the right balance could be especially difficult for multi-component foods, such as packaged pre-cut salads (Niemira and Fan 2006).

Choosing an optimal dose for particular produce items can be more difficult if the foods do not absorb irradiation evenly throughout single items or packages. Uneven irradiation can be caused by factors such as the irregular shapes of some fruits and vegetables, and variable textures and densities in single foods or in foods with mixed ingredients. When irradiation doses are absorbed unevenly, some areas in the food could get doses too low to control pathogens effectively, while other areas could absorb doses too high to avoid adverse sensory effects (Niemira and Fan 2006).

Uneven dosage is a particular concern with electron-beam irradiation, since the electron stream can penetrate only 2 to 3 inches into foods; gamma rays and x-rays, on the other hand, can penetrate 8 to 12 inches into foods of comparable density. Computer simulation suggests that the ratio of highest to lowest absorbed dose might be as high as 3.0 (e.g., 1.5 vs. 0.5 kGy) for some foods irradiated by electron beam (Niemira and Fan 2006).

Additional research is required to define optimal irradiation doses for numerous specific varieties of fruits and vegetables, and to identify other preservation techniques that, used in combination with irradiation, could enhance its desirable effects while mitigating its undesirable effects. As noted in the discussion of effectiveness against pathogens, above, these questions need to be addressed on a food-by-food basis in laboratory

studies, then further research would be needed to demonstrate that irradiation of specific fruits and vegetables is feasible and reliable on a commercial scale.

Are irradiated fruits and vegetables safe to eat?

Are they microbiologically safe?

The first and probably most important safety concern, already discussed, is whether the reduction in bacterial loadings that irradiation can achieve in produce, given the need to use lower radiation doses, will make irradiated fruits and vegetables "safe enough." This issue is closely coupled to the potential for re-growth of bacterial populations following irradiation, and to the nature of the foods themselves, which are usually not cooked and may be stored for up to two or three weeks after purchase before consumption.

The criterion frequently applied to other anti-bacterial food treatments is a reduction of 5 logs in pathogen loading. It seems clear that many forms of fresh produce cannot tolerate doses of irradiation needed to achieve that degree of reduction. Whether a less stringent criterion, such as a 3-log reduction, can reasonably be applied to produce, is not clear. A consensus definition of what is a sufficient pathogen "kill" in irradiated produce should be developed through an open process involving the affected stakeholders, which has not occurred. The question of what is "safe enough" in this context is thus unresolved.

Regardless of how (relatively) safe irradiated produce is objectively, some consideration also needs to be given to how safe it might be perceived to be. Concern may be warranted that consumers, retailers or others in the distribution chain might believe irradiated foods are sterile, and thus fail to observe necessary refrigeration and safe-handling procedures. This possible "false sense of security" could be addressed with consumer and industry education programs, which should be part of any implementation plans for irradiation of fresh produce.

What are the other safety concerns about irradiated produce?

Beyond the central microbiological safety issues, food irradiation in general, and specific proposals to use irradiation to control particular pathogens on produce items, raise safety concerns related to changes irradiation is known to cause, or hypothetically might cause, in treated foods.

Numerous expert authorities, frequently cited by irradiation's proponents, have reviewed the existing evidence and concluded that irradiated foods are safe (see FMI 2000, for a list of endorsing organizations.) Nevertheless, a number of significant unanswered (and sometimes, essentially unanswerable) questions remain about possible food safety risks irradiation could, at least theoretically, create. Even in the face of rather dogmatic expert assurances of safety, the lack of more definitive scientific evidence on several of these issues makes some people take a precautionary attitude toward irradiation, and gives its opponents a valid basis to assert that irradiation might create novel food safety hazards.

Indeed, it might. But whether these theoretical risks are genuinely worth worrying about is harder to assess. Key issues are briefly examined in the sections that follow.

Does irradiation produce harmful chemical changes in foods?

Since both the anti-microbial and the sensory effects of irradiation arise from changes in molecules and tissues produced by high-energy radiation, it is reasonable to ask what else irradiation does to foods.

A long-standing concern about irradiated foods in general is the possible creation of so-called "radiolytic products," i.e., compounds formed by reactions with the free radicals created by radiation. Formaldehyde can be formed by irradiation of carbohydrates, for example. Such radiolytic products generally are created at low levels, often lower than levels that occur naturally in foods or are produced in cooking (FMI 2000). Still, some advocates consider such increments to the natural toxic chemical content of foods to be an important undesirable side-effect of irradiation.

Some radiolytic products could be unique (i.e., formed only by irradiation), and some could be toxic substances. These are certainly theoretical possibilities. Since reactions can occur between free radicals formed by irradiation and any other molecules in foods, more or less at random, it is not possible to predict all the reaction products that might be formed, nor can we usually identify radiolytic products likely to be present in any given irradiated food. This creates a kind of "Catch-22" situation.

Since the identity of such unique radiolytic products is largely unknown, their presence cannot be tested for. It usually is not known what unique substances might be present, in what amounts, and we cannot isolate these substances and test them for toxicity. While we can infer that such compounds may be present in an irradiated food, we can neither confirm nor refute that possibility with scientific evidence, and there is no practical way to assess the risk they might pose. We simply have to deal with the uncertainty.

Furan in irradiated and non-irradiated foods

A more concrete concern arose a few years ago with the discovery that furan is formed in irradiated high-carbohydrate foods. For example, Fan (2005b) has shown that furan levels in apple and orange juices increased linearly with irradiation doses ranging from 0 to 5 kGy.

Furan causes cancer in rodents fed high doses, and its presence in foods, even at low levels, automatically triggers regulatory concerns. Furan levels in irradiated foods are in the low parts-per-billion range. Awareness that furan was produced in irradiated foods led FDA and industry scientists to test similar non-irradiated foods for furan; they found that cooking also produces furan in many foods, generally at higher levels than are found in irradiated foods (Olson 2004). The current focus has therefore shifted to the general problem of furan in foods (FDA 2004).

Nevertheless, in order to reach an approval decision on the FPA petition to irradiate fruit juices and possibly certain other kinds of produce, the FDA will need to assess any risks posed by furan in irradiated foods, and determine whether the risks are acceptably small. At this point, FDA does not appear to have reached a definitive conclusion.

Studies are under way now to shed more light on the mechanisms of furan formation in foods and the extent of human exposure to furan from foods, to support quantitative risk assessments. Until the needed data are gathered and analyzed, FDA may defer a decision on approval of irradiation for fruit juices and other high-carbohydrate foods.

What about chemicals that could migrate from packaging?

An earlier section noted that fresh fruit and vegetable food products can be irradiated in their packaging, as a "final step," which can be an advantage, since it reduces the risk of cross-contamination after irradiation. But the exposure of packaging materials to high-energy radiation, while those materials are in contact with foods, raises concerns about possible migration of packaging components into foods, or radiation-induced chemical reactions between packaging and foods. These are not unreasonable questions, and they can be resolved by well-designed research. But the technology often moves faster than the science, and much of the needed research in this case has not been done.

Considerable data exist on the effects of irradiation on some food packaging materials, and FDA has approved a list of packaging materials that may be irradiated (Niemira and Sommers 2006), but most of that data is from testing done decades ago. Information is needed on the potential effects of irradiation of specific fruit and vegetable foods in the packaging types and materials in which they are currently marketed (CDC 2005b). To support its assessment of whether irradiating packaged fresh vegetables, fruits, salads and the like raises any important new safety issues, FDA could ask the industries involved to provide more data on this issue.

What other food safety concerns does irradiation raise?

The world literature on food irradiation is immense, and within that large body of science there are some studies that have reported adverse effects in animals fed a single irradiated food over their lifespan. However, many other feeding studies have found no ill effects of irradiated foods. Such conflicting evidence is often encountered in health research, and at present, the consensus is that the evidence of a hazard is unconvincing (FMI 2000). This evidence does create some uncertainty, which decision makers evaluating the irradiation of fresh produce may need to acknowledge but cannot resolve.

Because irradiation kills spoilage organisms as well as pathogens, the concern exists that consumers might be misled into incorrect "common-sense" decisions about food safety. That is, they may conclude that an irradiated food that spent a few too many days in their refrigerator is safe to eat, because it doesn't look or smell spoiled. In theory, such a food could be loaded with pathogenic bacteria, but still appear "clean" to the senses. On the other hand, studies cited above suggest that spoilage bacteria re-grow after irradiation at similar rates to those for pathogens, which means off-odors and similar signs of spoilage probably would still be present to warn consumers (FMI 2000).

This concern cannot be addressed effectively in general terms. What is needed instead is specific information about pathogen re-growth and spoilage after irradiation at various doses for specific foods, in specific packaging, stored at specific temperatures and for specific lengths of time. Such data don't yet exist, but are needed so that regulators and industry can assess this safety issue on a case-by-case basis.

What's the bottom line? Is produce irradiation safe, or not?

That question can't be answered with a simple yes or no. But several additional points may help put the food safety risks of irradiation in perspective:

First, it is a truism, but absolute safety does not exist. Expecting food irradiation (or any other technology) to pose no risks whatsoever is applying an unrealistic and unreasonable standard. Nothing can meet a zero-risk standard.

What standards might be more appropriate? In general, the test applied under US food safety laws is "reasonable certainty of no harm." That translates into "fairly persuasive scientific evidence that the proposed treatment will not cause any significant adverse effects on public health." Again, this standard does not imply zero risk, but rather that any risks that do exist seem low enough, based on scientific evidence, to be acceptable.

The "reasonable certainty of no harm" standard requires somewhat subjective judgments by regulatory officials, which is a good part of what we pay them to do. FDA has to date concluded that irradiation of several food categories passes the test, i.e., is "safe enough," based on the available evidence. Irradiation of produce, although it differs from the other approved categories in several ways explored in this report, probably will also pass this test, eventually, but how long it may be until that happens remains to be seen.

A second perspective lies in the fact that almost all forms of food processing, including cooking, pose some risks. In fact, the known risks of many other food treatments appear to be substantially larger than those associated with irradiation. The furan issue, discussed above, is one example: Irradiation produces furan in certain foods, but cooking creates higher levels of furan. Grilling and broiling meats was shown, many years ago, to form a variety of toxic by-products in the seared areas on the meat surface. Specific compounds isolated from those charred areas were tested by toxicologists and shown to be mutagenic and/or carcinogenic, in several cases.

But we still eat cooked carbohydrate-containing foods, grilled meats and other foods that science has shown to pose small risks over the years. Clearly, cooking offers significant benefits, as well as risks. A properly grilled steak is not only free of (living) pathogenic bacteria; that delicious grilled flavor comes from many of those same chemical reactions that attracted the attention of the toxicologists.

In short, we don't judge most food treatments only by the risks they pose; we weigh the risks against the benefits, and judge a risk by whether it seems acceptable, not by its mere existence. This same risk/benefit balancing approach can reasonably be applied to food irradiation, and specifically to irradiated produce.

From that perspective, safety questions—other than the fundamental ones about reduced risk from pathogens—are probably not the aspects that will drive decisions about produce irradiation. The available evidence does not suggest any major or insurmountable safety issues, although a handful of probably small and quite uncertain risks require additional and thoughtful evaluation.

In the end, irradiation of fresh fruits and vegetables and related products will probably be judged "safe enough," if it proves to have substantial benefits. As previous sections have explained, the actual magnitude and practical attainability of irradiation's benefits in this context largely remain to be determined. Until much better answers are obtained to those questions, the safety questions cannot be sensibly resolved.

Are there other undesirable effects of food irradiation?

An important concern is that widespread use of irradiation on fresh produce could lead some growers, processors, distributors and consumers to be less aggressive in practicing other sanitation measures. Although everyone involved agrees, in theory, that irradiation is a supplemental tool, not a substitute for "farm-to-table" good management practices, their knowledge that produce was going to be irradiated, or had been irradiated, might dispose some actors in the food production chain to "cut corners." Both human nature and economics suggest that this is not an unreasonable concern.

Opponents of food irradiation often cite this as one of their largest worries about uses of the technology—that once implemented, it may devolve into a de facto "end-of-the-pipe" clean-up for a "dirty" production process, even if no one involved wants or expects that to happen. Whether such a scenario is likely with irradiated produce might be assessed by examining whether anything similar has taken place in the poultry industry, for example, where irradiation has been available for 15 years or so. This is another area of desirable research that has not been done.

Is irradiation of produce economically feasible?

The analysis required to answer this question definitively would be complex, but some general observations may suggest an answer. Key questions for economic research can also be identified to explore how viable irradiation of fruits and vegetables might be.

Costs and logistics

Building an irradiation facility costs several million dollars, and staffing and operating such a facility has significant ongoing costs. However, irradiated produce could become available without a need for irradiation plants built for that purpose.

When irradiated strawberries appeared on the market in the 1990s, they were irradiated at a plant in Florida used primarily to sterilize medical equipment (Morrison 1992). Most likely, a similar scenario would occur when and if irradiation of produce were approved by the FDA. Rather than invest in new plants to irradiate, say, spinach, produce marketers who wanted to use irradiation on spinach might contract with an existing facility (such as one that currently irradiates meat) to perform the service.

The logistics involved in transporting produce from its point of origin, to an irradiation plant, and then out to dispersed markets, could be formidable. Unless one imagines that produce-irradiation facilities would spring up quickly in dozens of locations near crop-producing centers (a very unlikely scenario, unless both the public and private sectors agree very rapidly that irradiation is effective, safe, and essential), the need to transport foods to and from the place(s) where irradiation was carried out could limit growth of the market for irradiated produce, in two ways. First, the price and cost of irradiated brands might be significantly higher. Second, it might prove difficult to funnel even a substantial fraction of a single crop like spinach, let alone multiple crops, through a small number of irradiation facilities.

A different scenario could be imagined, in which a large, centralized produce processor, who cleans and packs crops from dozens or hundreds of farms for a similarly large array of distributors and marketers, considered building an on-site irradiation facility. Large, centralized processors often serve diverse sectors of the produce industry. For instance, the processing company to which the *E. coli*-contaminated spinach associated with the outbreak in September 2006 was traced back was packing for both conventional and certified organic marketers, although at different sites (FDA 2006a). A large processing firm considering whether to irradiate produce on-site would need to determine how many of their growers and customers were interested in using irradiation. Whether it would be feasible to manage separate irradiated and non-irradiated product streams, and whether the irradiated part would generate enough income to justify the investment in irradiation, would likely then become the pivotal economic questions.

Unless a durable market demand for irradiated produce is identified, the idea of facilities dedicated to the purpose seems implausible. "Early adopters" in the produce industry, if there are to be any, will almost certainly rely on existing irradiation facilities, as noted. Whether and when the produce industry might begin building its own irradiation capacity would then be driven by the market, over a period of years.

Either approach entails logistical challenges and risks. Relying on outside suppliers for irradiation could require booking the use of an irradiation facility some time in advance. Whether growing conditions, the weather, the size and timing of the harvest and other variables familiar to fruit and vegetable growers would "cooperate" with such scheduling requirements might be a problem. On the other hand, if a produce processing center built its own irradiation facility with enough capacity to handle produce flows at peak harvest times, underutilization during less active periods might prove too costly.

Predicting future demand for irradiated produce

The produce industry may find a cautionary tale in the experience of Surebeam, a leading provider of irradiation for US meat processors. When irradiated beef was first offered for sale in 2000, Surebeam began irradiating millions of pounds of beef per year, and initially their business grew at 40 percent annually. But many assumptions Surebeam made about the market forces they expected to drive expanding sales of irradiated beef were flawed (Olson 2004). The company overbuilt its capacity, incurred unsustainable overhead costs, and filed for bankruptcy in late 2004 (Yovich 2004).

Irradiated beef is still available in US markets; other irradiation providers have stepped in to provide the service after Surebeam collapsed

(Olson 2004). But that market has grown more slowly than enthusiastic supporters of irradiation had predicted.

Future market developments for irradiated produce may be more difficult to predict than they were for beef. Not only is there a more diverse array of food-pathogen problems in the case of produce, but the basic questions about the effectiveness and acceptability of irradiation for solving those problems are less clearly answered than they were for beef.

Costs of regulatory compliance

An additional economic aspect is the cost of regulatory compliance. Food irradiation facilities are overseen not only by food safety agencies, but also by occupational health authorities (because of radiation and other hazards to workers), while the handling and transport of radioactive materials bring visits from environmental and transportation inspectors and the Nuclear Regulatory Commission. For companies that have operated irradiation facilities, dealing with the multiple requirements of overlapping agencies is a significant, but familiar, cost of doing business. On the other hand, if companies within the produce industry wished to begin operating a dedicated food irradiation facility, they might find the added regulatory burdens involved both a novel experience and a major additional expense.

The economic bottom line

Niemira and Sommers (2006) note that produce irradiation has a number of "ancillary" benefits and costs. On the positive side, irradiated fruits and vegetables have longer shelf life, reducing storage losses, and should sell at premium prices. But on the downside are costs such as the regulatory compliance burden, and probable needs for educational and outreach programs to address producer and consumer concerns about irradiation. With no experience selling irradiated produce to draw on, these costs and benefits cannot now be quantified. It is therefore not possible to assess how much more irradiated produce might cost than its non-irradiated counterparts, or how well it might sell at any price point.

Ultimately, the economic viability of irradiation for fresh produce will depend on two factors: Whether the produce industry decides that irradiation is necessary to ensure the safety of their foods; and whether consumers demand, or at least large numbers of them are willing to buy, irradiated produce at premium prices (see next two sections).

Will consumers accept irradiated produce?

Some will and some won't. Since irradiation is a prohibited practice under the National Organic Program rule, consumers who prefer organic foods will not have the option of buying irradiated organic produce (unless the rule were amended to allow irradiation, an unlikely prospect that would require a lengthy rulemaking process). For everyone else, consumers will need to weigh the pros and cons of irradiated fruits and vegetables and decide whether they'd like to try them.

There are many kinds of consumers with many different and mostly sensible concerns. Some consumers may be attracted by the claim of added safety to try irradiated produce, at least once. Others may simply be curious, or drawn by some "high-tech" panache. A key question is whether consumers who buy irradiated produce once will buy it again. If irradiated produce either has or is perceived to have lower quality than non-irradiated alternatives, and if it costs more, most consumers would probably not buy it for long, unless they believed they were getting something quite valuable in return.

Marketers of irradiated produce may therefore feel pressure to exaggerate any differences in safety between their products and competing products. But they would be constrained in this regard by legal and FDA regulatory labeling requirements. The law requires foods treated with irradiation to be clearly labeled as such. Some sellers view this as a "warning label" and fear that consumers are frightened by the word "radiation." But labeling foods as irradiated informs potential buyers about an important, distinguishing attribute of the product, what FDA calls a "material fact," and this requirement is unlikely to change.

Sellers who want to promote products as "safer" because they are irradiated can hardly complain about having to reveal the fact that those products have been irradiated. FDA regulations permit labels also to state the reason for irradiation; for example, "Irradiated to kill harmful bacteria." However, FDA's general labeling rules prohibit "misleading" label claims. In recent labeling disputes over genetically modified foods, FDA has made it clear that it considers label claims that imply that competing products are unsafe to be misleading, unless there is substantial scientific evidence to back that up. If irradiation is approved for fresh fruits and vegetables, extended discussion, and possibly FDA or FTC rulemaking on how the foods may be labeled and advertised, are likely to follow.

Experience with other irradiated foods suggests that most consumers are willing to buy them (FMI 2000). The anti-consumer stereotype propagated by some pro-irradiation advocates, i.e. that consumers are scared silly by irresponsible opponent claims about risks, is nonsense. Most consumers are open minded, and many are fairly well informed. They know enough or can learn enough about irradiation to make up their own minds about whether they'd like to try fresh produce that has been irradiated.

What factors influence consumer decisions about irradiated foods?

While consumers' minds are open, they are not empty; consumers will evaluate irradiated produce in the context of their pre-existing knowledge and preferences. Many may find this additional safety step reassuring, and buy irradiated produce because they perceive it to be safer. But many others may weigh the pros and cons of irradiated foods and decide they'd rather not buy irradiated produce.

Some decisions to reject irradiated produce will be made by risk-averse consumers who are aware of, and uncomfortable with, some of the unanswered safety questions about irradiated foods. Other consumers may be more worried about the use of a "technical fix" to clean up food just before it reaches the market. Many consumers would rather choose foods that they perceive to have been produced in ecologically sound ways, with careful attention to the GMP and GAP measures that aim to keep harmful bacteria out of the food supply in the first place. Some consumers may turn to organic produce because it is not irradiated, while others may avoid organic foods for exactly the same reason. Consumers' diverse food choices rest on both evidence and lifestyle preferences, and in the end they are largely value judgments that are consumers' to make.

How well irradiated produce is accepted by consumers (assuming it reaches the market) will probably depend most heavily on two factors: Whether a convincing case can be made that irradiation adds measurably to the safety of the produce treated with it; and whether irradiated fruits and vegetables look, taste, smell and feel as appealing as non-irradiated versions of the same foods.

To some extent, the success of irradiated produce may turn on luck. If the first few fresh fruit and vegetable products irradiated for safety reasons turn out to be "winners," i.e. as appealing as competing brands, demonstrably safer, and affordable, the precedent they set may carry over to other products. But if the initial offerings are flawed, don't taste very good, cost too much, or are found by credible independent tests to contain just as many dangerous bacteria as non-irradiated varieties, that could give irradiated produce a "bad reputation" that might be difficult or impossible to overcome.

This analysis ignores other factors that also influence consumer choices when they buy fresh produce, including brand loyalty, personal tastes and sensory preferences, and for many, a desire to support local growers.

The bottom line is, some consumers will buy irradiated produce for a variety of reasons, and some will choose not to buy it, for a variety of reasons. People's reasons for buying or not buying particular foods are complex, and the introduction of irradiated produce into the marketplace will not cause a tidal shift in factors that influence those decisions. It might cause a ripple or two, at most. If irradiated produce offers values that consumers are willing to pay for, the market should eventually sort that out.

Is irradiation of produce necessary?

In the end, the primary factor other than clear consumer demand that could drive produce industry members to adopt food irradiation would be a conviction that irradiation truly is necessary to bring produce safety to acceptable levels. Being necessary is different from being (potentially) useful; it is different from being effective (if that were established), or from being economically feasible, or from being acceptable to consumers.

What does "necessary" mean?

Food irradiation would be necessary if a strong case were presented that problems caused by pathogens on produce cannot or will not be solved without using irradiation. That case has not been made, and is difficult to make, given evidence reviewed in this report. But irradiation of produce might be judged necessary in the future, if certain conditions are met, such as some or all of the following:

- If intensive efforts to prevent pathogen contamination of produce using other methods prove insufficient or unsuccessful;
- If pathogens like *E. coli O157:H7* and *Salmonella* continue to trigger major outbreaks of produce-borne illness, with unacceptable public-health consequences;
- If concern about pathogens in produce reverses the long-term trend toward increased per capita consumption of fruits and vegetables, and sales decline;
- If exports of US fruits and vegetables are restricted because the produce fails to meet microbiological safety standards of importing countries;
- If strong additional measures are required to restore the confidence of consumers and trading partners in the safety of US produce; and
- If irradiation can be convincingly shown to be effective at substantially reducing the frequency and scope of future outbreaks of produce-related food poisoning.

Stated simply, these conditions have not been met yet, and while irradiation of produce has drawn a lot of interest as a potential solution, it is not an actual available solution at this point.

So, what should be done now?

One option is to assume that irradiation will eventually be judged essential for produce safety, and vigorously pursue that objective. Costly research would need to be planned, coordinated and carried out and results would need to be published and analyzed. FDA approval would have to be secured. The logistics of getting fruits and vegetables treated at existing or new irradiation facilities would have to be worked out. Market research on consumer responses to irradiated produce would need to be carried out. And much more. Whether irradiation ultimately does or does not turn out to be a necessary food safety tool for the produce industries, there can be little doubt that implementing this tool will have huge up-front costs, and will take years to happen.

It is reasonable to ask, why go through all that? Aren't there other currently available, proven, potentially equally effective and possibly lower-cost steps the produce industry could implement that could (further) reduce pathogen contamination, and satisfy the industries, governments and consumers that the problems are well under control?

Of course there are. Many GMPs and GAPs have long been used and can now be used, possibly in new combinations, to enhance the microbiological safety of produce. More are actively being developed. Most of the technologies involved are well-tested and have few of the downside risks associated with food irradiation.

Research will be needed, of course, to develop and refine new applications of existing GAPs and GMPs to fit specific pathogen-food combinations

Box 4.

Resources for Managing Pathogens in Produce

The FDA, USDA and other expert bodies have compiled extensive documents on GMP, GAP, HACCP and other systems and methods for preventing or reducing bacterial contamination of fresh fruits and vegetables, and made this information available on the internet. Useful sources include:

FDA GMP/GAP Manuals for produce:

Fresh fruits and vegetables: http://www.foodsafety.gov/~dms/prodguid.html

Fresh-cut fruits and vegetables: http://www.cfsan.fda.gov/~dms/prodgui2.html

Sprouts: http://www.cfsan.fda.gov/~mow/sprouts2.html

Melons: http://www.cfsan.fda.gov/~dms/melonsup.html

Tomatoes: http://www.cfsan.fda.gov/~dms/tomatsup.html

Lettuce and leafy greens: http://www.cfsan.fda.gov/~dms/lettsup.html

FDA HACCP Information: http://www.cfsan.fda.gov/~lrd/haccp.html

USDA HACCP Guidelines: http://www.fsis.usda.gov/Science/PR_&_HACCP_Guidance/index.asp

National Advisory Committee on Microbiological Criteria for Foods, HACCP Guidelines: http://www.fsis.usda.gov/OPHS/NACMCF/past/JFP0998.pdf

now known to be important for produce safety. There may well be competition for limited research funds between studies to improve applications of existing options for immediate use and other studies to develop data needed to apply irradiation to these problems in the indefinite future.

Because many current GMPs to control bacteria on produce are relatively ineffective at removing pathogens, preventive measures are essential, all along the farm-to-table chain of production. Preventing initial contamination of produce, and preventing the growth of pathogen populations on produce, are both critical elements (IAEA 2006).

Information on GAPs and GMPs that can help prevent microbial contamination of foods is widely available and readily accessible on the internet (see Box 4), as is information on HACCP systems (Hazard Analysis by Critical Control Points). HACCP has been used to manage microbial hazards in meat and poultry (required by USDA regulation); HACCP systems are already used against similar hazards by some fruit and vegetable producers, and their use could be expanded, whether voluntarily by the industries, or required by (future) regulations. Regulatory agencies are eager to share knowledge and experience with the industries involved to assess and implement any measures that can help reduce current problems of pathogen contamination in produce.

Given the urgency of solving these problems, the industry seems well advised to act now, using appropriate available options, rather than to wait as long as it may take for produce irradiation to be adequately investigated and to obtain FDA approval. If members of the produce industry act now, as they must, by the time food irradiation for produce finally “arrives,” some years down the road, it may no longer be needed.

At minimum, final decisions about using irradiation on produce will need to be made in the context of a future in which multiple currently available controls have already been implemented. Only then, not now, can the produce industry reach adequately informed judgments about how necessary food irradiation might be for produce safety.

Conclusion

Food irradiation certainly can kill bacteria, and in theory it could be a useful tool for managing some pathogens in fresh produce. But such applications are years or decades away from being a practical reality, and are not currently permitted by the FDA.

Extensive research is needed on irradiation of specific foods and food products to address an array of currently unanswered questions: What irradiation doses are effective against pathogens of interest on specific foods? Can irradiation reduce pathogen loads initially to acceptably safe levels, while effectively preventing re-growth? Will the sensory quality of irradiated produce be acceptable to consumers? Can combinations of irradiation with other food processing measures and/or "upstream" interventions in the food production chain boost the effectiveness and limit the undesirable side effects of the irradiation step? What combinations work best for what foods? Is irradiation of produce economically and logistically feasible? Will irradiated fruits and vegetables be embraced or rejected by the industry and the public?

The lack of good scientific answers to these questions, not political opposition or timid bureaucracy, accounts for the slow pace of progress toward using irradiation to control problems like *E. coli O157:H7* in lettuce and spinach. Because of the growing need for tangible improvements in produce safety, other approaches that do not have such large up-front research costs, such as GMP, GAP and HACCP systems, must be pursued and are likely to be implemented more rapidly, at lower cost, and with far less potential for controversy than irradiation could be.

Ultimately, market forces will determine whether food irradiation plays a significant role in the effort to improve produce safety. If the produce industries, regulators and the other concerned stakeholders perceive that pathogen contamination of fresh produce has been effectively addressed, and particularly if there is a significant downturn in the incidence of produce-related outbreaks of illnesses due to *E. coli* and other pathogens in the next few years, interest in using food irradiation on produce is likely to wane.

On the other hand, if the near future includes several additional highly-publicized food poisoning outbreaks linked to fresh produce, if "upstream" GMP, GAP and HACCP countermeasures are slow to be implemented because of cost or feasibility, or if those steps the industry has taken are perceived as insufficient, demand could arise for further and more effective improvements in the microbiological safety of fruits and vegetables.

In this latter scenario, the potential added value irradiation might offer in a market hyper-concerned with produce safety could convince some food producers to pursue using it, and pressure might grow for the FDA to approve irradiation for fresh produce. Given sufficient scientific evidence of effectiveness and safety, FDA would probably grant the approval, but when a decision might occur is hard to predict.

While FDA approval would certainly boost prospects for irradiated produce, the market success of irradiated fruits and vegetables is far from guaranteed. Sales of irradiated beef and chicken, foods more widely recognized as sources of food-borne illness, have been modest at best. Whether irradiated produce would meet consumers' expectations in terms of safety and quality, and whether a robust demand for it would persist and foster growth of the market, are far from certain.

The most probable future scenarios thus range from no change (no irradiation of fresh produce to kill pathogens at all), to the introduction and slow expansion of a market niche for irradiated fruits and vegetables. But even in the latter case, most produce will remain non-irradiated for the foreseeable future.

Sellers of both irradiated produce and non-irradiated fruits and vegetables should be able to appeal to different sectors of the buying public. Credible safety claims should apply to both categories of products. Irradiation is an additional, incremental safety measure, not a complete guarantee of safety in and of itself, while good farm-to-table risk management systems, effectively implemented, should provide comparable safety without irradiation. In all likelihood, irradiated fruits and vegetables would remain a small and specialized market sector, interesting in its own ways, but posing no unusual marketing challenges for producers of non-irradiated produce, which will remain the vast majority of products offered to consumers.

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