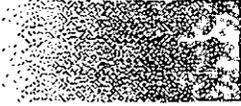


NLWJC - Kagan

DPC - Box 008 - Folder 004

**Consumer Protection - Food Safety
Irradiation**

Cms pro - food safety -
irradiation



Jerold R. Mande

12/04/97 02:52:36 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP, Donald H. Gips/OVP @ OVP, Toby Donenfeld/OVP @ OVP

cc:

Subject: NYT's Food Safety Series

I wanted to make sure you noticed that the NYTs ran the first part of its four part series on food safety today. Actually, today's story, which was on food irradiation, was suppose to be the third piece in the series, but it was moved to first following FDA's irradiation decision on Tuesday. HHS is checking on whether we will see the other three pieces anytime soon.

Today's story:

Is Irradiation the Magic Bullet Against Food Poisoning?

By GINA KOLATA with CHRISTOPHER DREW

MULBERRY, Fla. -- Five years ago, Harley Everett envisioned a burgeoning industry that would rid meats, fruits and vegetables of harmful bacteria by bathing them briefly in gamma rays. His company built an irradiation plant, tucked away on a dusty road in this phosphate mining town. But business is hardly thriving.

His plant remains the only one in the nation built solely to irradiate food. Down the hall from Everett's office on a recent day, behind 6-foot-thick concrete walls, slender rods of radioactive cobalt glowing ice blue waited uselessly in a deep pool of water. The plant was silent, its parking lot all but empty. There was no food to irradiate.

Everett, the executive vice president of Food Technology Service, said the plant irradiates a few items for people who cannot take a chance on food poisoning: poultry for hospital patients with weakened immune systems, all the food the astronauts eat. It treats some strawberries, in season, spices and a few potatoes and onions. That is about it.

But Everett is newly hopeful that the nation's long indifference to irradiation may be about to change. As politicians and the public grow increasingly alarmed by a new series of outbreaks of food poisoning, scientists and the food industry have renewed their search for a magic bullet.

Tuesday, the Food and Drug Administration approved the use of irradiation on red meat, the first step in the regulatory process that could allow beef companies to start using this tool by next summer.

Everyone agrees that Everett's system works, and irradiation is not expected to add more than a few pennies to the cost of a pound of ground beef at the largest meat plants. The meat industry lobbied hard for approval of it and some leading companies see it as the a sure-fire way to eliminate any deadly E. coli O157:H7 bacteria and other new hazards from hamburgers and other popular foods.

But the public has shown little confidence in scientists' assurances that irradiated food is safe. There is almost no demand for irradiated chicken, fruits and vegetables, even though such products were approved years ago. One vocal consumer group, fanning fears about radiation hazards, has threatened to boycott any store that sells irradiated foods.

And the big question now is whether the recent outbreaks, dramatized by a huge recall of hamburgers at Hudson Foods last August, have convinced consumers that the dangers outweigh their fears about the cure.

As an incentive for processors and consumers, the Agriculture Department is considering allowing companies to label irradiated products as free of dangerous bacteria, said Dr. Daniel Engeljohn, who is writing final regulations on irradiation.

But even the nation's largest beef producer has reservations.

Although many scientists have said that irradiation does not cause significant changes in meat, the meat producer, IBP Inc., based in Dakota City, Neb., has found that the process slightly alters both the flavor and color of ground beef. Irradiation darkened the color of the meat and changed its taste in a "noticeable enough" way to cause concerns within the company, said Gary R. Mickelson, an IBP spokesman.

The company will need to test-market irradiated beef before deciding whether to adopt the process, Mickelson said, adding, "It will ultimately be up to the consumer to determine if it is acceptable."

Mark Klein, a spokesman for the nation's second-largest beef company, Excel Corporation, a subsidiary of Cargill Inc., said: "We're in favor of irradiation as an additional tool. And if the technology works, we will use it."

Irradiation has run into some practical problems with other foods, especially with the most delicate fruits and vegetables, which can wilt under the doses needed to kill harmful bacteria. But other new safety methods are drawing attention as well.

Some meat and produce companies are adopting new technologies that kill pathogens, or microorganisms that can cause disease, with blasts of steam, light beams or ozone, a disinfectant long used in drinking water. And scientists are working on a vaccine to wipe out harmful bacteria carried by cattle and chickens at the safest point possible, before they ever leave the farm.

But in recent months, attention has increasingly turned to irradiation. The continuing battle over irradiation, whose supporters long for a more appetizing name, like "cold pasteurization," illustrates the difficulties that lie ahead as scientists and the food industry search for the best way to eliminate such dangerous pathogens as E. coli from the nation's food supply.

New safety methods -- no matter how much support they have -- are likely to face a variety of hurdles, including financial risks, intensive politicking by mighty industry lobbyists and consumer groups, and, ultimately, a wary public.

"Everyone wants to be second" to try irradiation, said an executive at a large restaurant chain, who asked not to be identified because his company's plans are not public. Moreover, he added, "the bigger they are, the more they want to be second."

If it catches on, irradiation might end up being used as the ultimate insurance for the most vulnerable products, like ground beef and poultry. But in the end, many experts say, no one method is likely to be a panacea for food.

"Irradiation may be helpful, and it may play a very important role in the future," said Dr. David A. Kessler, a former FDA commissioner. "But I don't think it's going, by itself, to get us where we need to be. It's not going to work if companies think they don't have to keep up with basic sanitary practices, and that they can just zap it all at the end."

But even as the questions persist, many regulators and food industry executives agree that this is irradiation's moment, a time when the government's attention, and the public's, are focused to an unusual degree on a method with an unappealing name that, its supporters hope, will eventually be on labels in supermarkets across America.

Irradiation: What It Is, How It Works

The idea of irradiating food first surfaced just after the turn of the century, and it began to take hold during World War II, when scientists working for the Army found that ground beef stayed fresh longer if it was exposed to X-rays.

The concept is simple: Irradiation can kill bacteria that can cause food poisoning by shattering their genetic material. Radioactive rays from sources like rods of cobalt are aimed at containers holding food and kill the bacteria as they pass through the food, leaving no residual radioactivity behind, scientists say.

The FDA approved several limited uses of irradiation -- the first was to help the Army preserve canned bacon -- in the early 1960s. But it rescinded the approval for canned bacon after a few questions were raised about irradiation's effect on laboratory animals in the late 1960s, casting suspicions on the process that persist even though most leading medical and scientific associations have since declared that it is safe.

Since then, the FDA has changed its view. The agency approved the irradiation of spices, fruits and vegetables in 1986 to destroy insects and mold, and it authorized the irradiation of chicken in 1990 to kill bacteria like salmonella or campylobacter, which are the two biggest causes of food poisoning in the United States.

The petition seeking FDA approval to irradiate red meats was submitted in August 1994 by Isomedix, a company based in Whippany, N.J., with 16 plants that irradiate medical devices and food cartons. Few people realize it, but there are about 60 irradiation plants in the United States and they sterilize a surprising array of items, from nipples on baby bottles to tiny containers holding coffee cream.

Studies show that irradiation can essentially eliminate the disease-causing bacteria like the E. coli O157:H7 that has killed people who ate infected hamburger meat. It also can kill salmonella in fish, just as it does in chicken, and the FDA also is examining whether to approve it for seafood.

Industry officials say it is less likely to be used on steaks, roasts and other slabs of meat, where any contamination lies on the surface and can easily be washed off in the plant or killed through cooking.

But there is growing pressure from fast-food restaurants and consumers to improve the safety of ground beef. A single hamburger can contain bits of meat from dozens of cattle, the primary source of E. coli, and the bacteria can survive inside the hamburger patty unless it is thoroughly cooked at a high temperature.

The government became so concerned about the new strain of E. coli that in 1994 it classified it as an adulterant in ground beef, meaning that processors would have to recall any raw hamburger containing the bacteria.

And increasingly, scientists have been saying that the food industry should eliminate such hazards, rather than leaving safety up to the diligence of each consumer.

The Safety Debate

Most infectious-disease specialists and public health experts say the science and benefits of irradiation are well established.

Over the years, researchers have focused on two main concerns -- whether irradiation can strip food of vitamins or create dangerous byproducts that could cause cancer or other health problems in people who eat the food.

But scientists who have studied irradiation say neither issue poses a serious problem, and irradiation has been endorsed for years by groups like the World Health Organization and the American Medical Association.

"My sense is that there is no rationality to the arguments against it," said Dr. Sherwood Gorbach, a professor of community health and medicine at Tufts University School of Medicine.

There is no doubt that irradiation -- just like roasting, frying or barbecuing -- causes microscopic changes in the chemical composition of food. One fear, cited frequently by Food & Water, a consumer group based in Walden, Vt., that is the main opponent of irradiation, is that the process might create what are called "unique radiolytic byproducts," or possibly harmful new compounds that are unlike any created by other types of cooking.

Most scientists doubt that any such compounds exist. An FDA task force estimated in the late 1970s that if they do, the amounts too negligible to cause any harm.

Michael Colby, head of Food & Water, dismissed such research and said, "The FDA is flying on a wing and a prayer saying it's OK."

And although radiation can slightly reduce the amount of vitamin C in a piece of fruit like an orange, "there is more variation from one orange to another orange on a tree than from one that was irradiated and one that was not," said Dr. Christine M. Bruhn, the director of the Center for Consumer Research at the University of California at Davis.

In pork and chicken, Dr. Bruhn added, irradiation can reduce the amount of thiamin and riboflavin in the meat from 0.01 to 1.5 percent, an amount within the normal variation between one pork chop and the next.

Despite IBP's findings of slight changes in color and taste, other researchers have found none. Dr. Elsa Murano, a food safety microbiologist at Texas A & M University in College Station, said that in taste tests, trained experts found no significant difference, except in one area. "Some panelists said the irradiated beef patties were more tender," Dr. Murano said.

She said that the inability of scientists to find distinct differences between most irradiated and non-irradiated foods "is the major evidence that it doesn't do anything weird to the food."

The nation's most influential consumer groups accept these findings. Asked if there is any danger in eating irradiated food, Michael F. Jacobson, the executive director of the Center for Science in the Public Interest in Washington, said: "No. The loudest critics have contended that irradiation produces danger chemicals. But if it does, the amounts seem vanishingly small."

Whither Consumers?

Ultimately, the public will be the ultimate arbiter of irradiation's future.

Consumer misperceptions have lingered despite all the evidence to the contrary -- a situation that some compare to the worries that first greeted the pasteurization of milk and the fluoridation of water.

A CBS poll in August, for example, found that only 12 percent of respondents favored irradiation.

And while nearly 40 nations have approved at least limited use of irradiation, only a few, like France, where many chickens are irradiated, have made much use of it.

But Dr. Bruhn maintains that the notion of overwhelming consumer resistance "is a myth."

For example, Dr. Anna V.A. Resurreccion, a professor of food science and technology at the University of Georgia, showed 126 study participants a slide show on irradiation, then observed how they behaved in a simulated supermarket. Eighty-five percent bought irradiated chicken.

She also surveyed consumers, with no information given. And she found that most of the respondents said they were less concerned about irradiation than pesticide residues, animal drug residues, growth hormones, food additives and bacteria.

That is no surprise to James Corrigan, president of the Chicago area store Carrot Top, which has been selling irradiated fruit since 1992. The required sign announcing that the food has been irradiated is no deterrent to many Carrot Top customers.

"When I got started, I offered them a choice, to see if they'd buy it," Corrigan said. He added that if the food languished unsold, he would assume there was no market for it. "But that's not what happened," Corrigan said. Now he flies in exotic Hawaiian fruits that otherwise would be barred from the mainland for fear of fruit fly eggs, irradiates them at a nearby plant that was built to sterilize medical supplies, and does a brisk business.

When Corrigan first said he would sell irradiated fruit, Food & Water, the group that opposes irradiation, warned him not to try. "They took out radio ads in Chicago and passed out fliers in a number of stores calling for a protest rally in front of my store." But on the day of the rally, "no one showed up," Corrigan said.

Food & Water also has tried to pressure poultry companies to keep them from using irradiation. But the industry has been selling all the billions of chickens it can process without irradiation, and so it has seen little need to bother with it.

Everett, at his forlorn irradiation plant in Mulberry, said the food companies have another worry. In telling him they don't need his services, some have said: "You want us to put that irradiated food out there next to the non-irradiated food and say, 'This is clean and this isn't?'"

Consumers around the nation are as divided as ever about whether they would welcome irradiation as the magic bullet of food safety.

In Seattle, where the dangers of E. coli first emerged in 1993 when hundreds of people who became ill from eating undercooked hamburgers, Marie Lovitt, a student at Seattle Central Community College, said she welcomed irradiation and would even pay more for treated meat. "If it's going to cost more to save lives, it's worth it," she said.

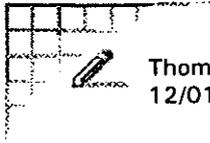
But in New York City, Judy Nurse, a child care worker, was wary. "They give radiation for cancer,

so I don't think it's a good idea for humans to eat it," she said.

Tony Guggino, a cameraman from Bergen County, N.J., said he would buy it. "Everything I've read about it says it is safe," he said.

But Guggino had to agree with his friend Marvin Welkowitz, an audio technician from Nassau County, N.Y. "Irradiation helps in the manufacturing process," said Welkowitz, "but once it gets to the local market, the meat still has to be handled properly. If it's not handled right in the market, it can still get contaminated."

Cons pro -
- food safety -
irradiation



Thomas L. Freedman
12/01/97 02:59:24 PM

Record Type: Record

To: Elena Kagan/OPD/EOP
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP
Subject: Food Irradiation Update

FDA called to give us a heads up that they will be approving the petition by Isomedics to approve use of a food irradiation technique for beef on Tuesday. They pointed out they try and keep a wall between the WH and these decisions. O'Hara at HHS advises we try and keep some distance from the issue, the food safety community has some splits over it: it definitely cleans up the foods, but some groups have concerns about its effects on the foods (toxicology and nutritionally) and there may be some concern about the facilities that perform the irradiation as there is waste from the irradiation process. FDA and HHS are sending over a list of Q and A's and a press release. They thought they were sending something through public affairs to McCurry. I'll get you more as I get it.

Other Facts

1. Irradiation has previously been approved for use in chicken, turkey and fruits. Consumer concerns have kept it from widespread use.
2. Before this can be used USDA will still need to issue an implementation order which could take several months.
3. FDA says the food would be labeled irradiated so customers could know what they are buying.
4. They are uncertain how much attention it will get but plan to use Mike Friedman to talk about it.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

DRAFT

P97-
 FOR IMMEDIATE RELEASE
 Dec. 1, 1997

FOOD AND DRUG ADMINISTRATION
 Arthur Whitmore: 202-205-4177
 Broadcast Media: 301-827-3434
 Consumer Inquires: 800-532-4440

FDA APPROVES IRRADIATION OF MEAT FOR PATHOGEN CONTROL

The Food and Drug Administration today approved irradiation of meat products for controlling disease-causing micro-organisms. The approval applies to fresh and frozen red meats such as beef, lamb, and pork.

"Irradiation of meat could prove to be another important tool to protect consumers from food-borne disease," said Michael A. Friedman, M.D., Lead Deputy FDA Commissioner. "The process has been shown to be safe and to significantly reduce bacterial contamination."

This approval is based on FDA's thorough scientific review of a substantial number of studies conducted worldwide on the effects of irradiation on a wide variety of meat products. The studies included examination of the chemical effects of radiation, impact on nutrient content of irradiated products, potential toxicity concerns, and effects on microorganisms in or on irradiated products. FDA concluded that irradiation is safe in reducing disease-causing microbes in or on meats, and that it does not compromise the nutritional quality of treated products.

FDA has previously approved irradiation of poultry to control pathogens, of pork for control of the trichina parasite,

-More-

ATTENTION TV BROADCASTERS: Please use open caption for the hearing impaired.

Page 2, P97-40, Meat Irradiation

of foods such as fruits, vegetables, and grains to control insects, and of spices, seasonings, and dry enzymes used in food processing to control microorganisms.

Food products are treated by subjecting them to radiation from radioactive or machine sources, which kills significant numbers of insects, pathogenic bacteria and parasites. Irradiation does not make food radioactive, nor does it noticeably change taste, texture, or appearance.

Irradiation of food products to control food-borne disease in humans has been generally endorsed by the United Nation's World Health Organization and the American Medical Association.

Disease-causing microorganisms that can be controlled by irradiation include *Escherichia coli* 0157:H7 and *Salmonella* species.

FDA's approval is the latest action by the Clinton Administration to take positive steps to reduce the number of consumers suffering from food-borne pathogens. Other steps include the implementation of mandatory Hazard Analysis and Critical Control Point (HACCP) safety programs at seafood, meat, poultry processing plants; expansion of the nation's network of surveillance sites for food-borne disease; funding additional research on food-borne disease control and detection; increasing the number of inspectors and inspections of domestic and imported produce; and implementing industry and consumer education programs on reducing food-borne illness risks.

-More-

Page 3, P97-40, Meat Irradiation

Irradiation, although a potentially useful tool for helping reduce risk of food-borne disease, is a complement to, not a replacement for, proper food-handling practices by producers, processors, and consumers.

This approval is in response to a petition filed in August 1994 by Isomedix Inc. of Whippany, N.J.

###

Meat Irradiation Qs and As

What is irradiation?

Irradiation is the application of radiant energy (radiation) to a target material. Various forms of radiant energy include: microwave and infrared radiation that heat food during cooking; visible light or ultraviolet light used to dry food or kill surface microorganisms; and ionizing radiation that can penetrate deeply into food, killing microorganisms without raising the temperature significantly. Ionizing radiation, resulting from cobalt-60, cesium-137, x-ray machines, or electron accelerators, is the type that has been recently approved for treating meats. Irradiation is also a common way of sterilizing disposable medical supplies, such as syringes and surgical gloves.

Does irradiation leave any radioactivity behind -- even trace amounts?

No. Irradiation processing does not make anything radioactive, and does not allow any radioactive substance to touch food.

To what foods does this new approval apply?

It applies to red meats (such as beef, pork, or lamb) and to certain products made from that meat, including ground meat, whole cuts, and organ meats.

Are there other foods for which irradiation is approved?

Irradiation has already been approved to control insects in foods where they may be found, to inhibit ripening or sprouting of fresh fruits and vegetables, to control the parasite in pork that can cause trichinosis, to control pathogens in poultry, to control microbes in enzymes, spices and seasonings, and to sterilize meats for astronauts' space meals.

How long has irradiation been approved for these uses?

FDA's first approval for an irradiated food was in 1963, to control insects in wheat. Since then, there has been a long and gradual expansion of approvals including spices in 1983, a general revamping and expansion in 1986, poultry in 1990, and meat for astronauts in 1995.

What food-safety issues does irradiation address?

Irradiation can reduce the number of pathogenic organisms in food. However, it is important to recognize that different organisms have different sensitivities to irradiation and that, while irradiation can kill microorganisms, irradiation does not leave a residual antimicrobial protection against growth of surviving microorganisms or recontamination.

Why does industry want it?

Irradiation has the capability of reducing the number of microorganisms in food. While irradiation may not be the treatment of choice for controlling pathogenic organisms in all cases, industry generally prefers to have multiple options available to ensure safe food.

Does irradiation change the nutritional content of meat?

As with other methods of food processing, irradiation of meat can cause losses of some vitamins. Irradiation of meat in a frozen state, and under reduced oxygen levels (vacuum packaging), tends to minimize vitamin losses. Overall, FDA has concluded that irradiation of meat and meat byproducts will not adversely affect the nutritional adequacy of consumers' diets.

Does irradiation affect the taste of meat?

Irradiation can, but does not necessarily, affect the taste of meat depending on the radiation dose and the conditions of irradiation, e.g., whether the meat is frozen or vacuum packed. For irradiation to be successful in the marketplace, conditions must be established such that the irradiated product is acceptable to the consumer.

When can consumers expect to see irradiated meat on the market shelves?

That will depend on a series of decisions and actions taken by the industry. Ordinarily, before companies adopt a new technology they will make cost/benefit estimates and marketing assessments and pilot test those applications that look economically favorable. If irradiation were to be applied on a large scale, appropriate facilities would need to be built. FDA has no way to forecast the results from such activities.

Moreover, USDA must issue a regulation permitting the use in meat processing plants, which will also specify how irradiated meat products must be labeled.

Why don't we see irradiated product for sale in the marketplace?

At least three things must occur for such a product to be common in the marketplace. First, government rules must allow for sale. Second, manufacturers must be convinced that it is in their interest to become competent in a new technology and to invest in developing a product commercially. Third, consumers must want to buy such products, thereby encouraging further investment from manufacturers.

Students of consumer behavior often speculate that many people have a general fear of anything to do with radiation, and will not purchase irradiated foods. However, to date, consumers have rarely had an opportunity to make such a choice. Reports of occasions where irradiated foods have been offered for sale do not show consumers being unwilling to buy irradiated foods.

Will meat be labeled so that consumers will know that it has been irradiated?

Yes. Meat products are regulated by USDA under the Federal Meat Inspection Act. Therefore, a regulation will need to be issued by USDA before any labeling is required. Although it is not now certain exactly what the regulation will state, it will most likely be similar to that of the irradiated poultry regulation, which requires a special green logo, as well as a statement of "treated with radiation" or "treated by irradiation."

Doesn't the recent FDA reform act address labeling for irradiation?

Yes. It restricts the FDA from requiring a type size larger than that required in an ingredient statement on products regulated under the Food, Drug and Cosmetic Act (which does not cover meat). However, because meat is regulated under the Meat Inspection Act, which is administered by USDA, the new FDA reform law does not directly affect USDA's authority in this area.

How long did it take FDA to act on irradiation for meat?

The petition requesting approval for meat irradiation was filed with FDA on August 25, 1994 -- 3 years and 3 months ago.

Why did it take FDA so long to approve irradiation for meat?

FDA reviewed the large body of relevant data in its files, a considerable collection of data submitted by the petitioner, as well as the scientific literature relevant to this decision.

Some of the issues that needed to be addressed include:

- Will irradiation generate chemicals in meat that would be toxic in the amounts that people are to likely consume?
- Will irradiated meats provide adequate nutritional value?
- Will irradiation conditions allow some harmful bacteria to remain and cause the meat to become more hazardous?

Answering these questions required significant investigations of radiation chemistry, dietary exposure, toxicology, nutrition, and microbiology.

Why does FDA call irradiation a "food additive"?

FDA does not call the irradiation process itself a food additive. In 1958, the U. S. Food, Drug, and Cosmetic Act was amended to require premarket approval for use of a food additive, and a "food additive" was defined as any substance the intended use of which may be reasonably expected to

result in its becoming a component or otherwise affecting the characteristics of any food, (including "any source of radiation" used to prepare, process, or treat food). Thus, Congress, through the Food Additives Amendment of 1958, determined that irradiation should be subject to premarket review.

What were FDA's major concerns about irradiation as a food processing technique?

The concerns are the same as with any food processing technique: that irradiated meats 1) would be as nutritious as non-irradiated meats; 2) that no harmful byproducts would be formed in the meats; and 3) that irradiation would not set up conditions that would allow meat to become hazardous (for example, by preferential growth of relatively radiation-resistant bacteria) under anticipated conditions of handling and storage.

Why is FDA approving irradiation in the first place? Wouldn't it be better to prevent contamination of meat with harmful microbes?

First, the law requires approval of petitions for the use of a food additive when that use has been shown to be safe. While this places a burden of proof on a petitioner, FDA cannot arbitrarily deny approval when that burden has been met.

Second, while striving to prevent pathogens from contaminating meat is the most important step to assure safety, it is not the only step. Safety is assured better when multiple actions are taken to reduce the probability of a hazard. It is in everyone's interest to take every reasonable step to improve the safety all foods, including meat, and irradiation can be an important tool to help achieve the goal of safer meat.

Does radiation kill all harmful microbes in meat?

This will depend on which harmful microbes are present and in what amounts. Irradiation at the doses approved does not eliminate every single microorganism from meat, but will reduce their numbers substantially. Furthermore, irradiation cannot prevent recontamination in the home or restaurant and cannot be relied on as the sole assurance of safety, but it does reduce harmful organisms to much lower, safer levels. It is important to remember that irradiated meat still must be properly handled, processed, and stored -- just like non-irradiated meat -- to ensure its safety.

Does irradiation solve all food-safety problems?

No. Irradiated meats still must be properly handled, processed, refrigerated, and stored, just like non-irradiated meat, to ensure its safety. Irradiation is a complement to, not a substitute for, sound sanitary meat production and manufacturing practices.

What are the concerns of those who oppose irradiation for meat?

Some people have expressed concern about the chemical changes that irradiation can cause in

meat, or about the possibility that nutrients may be lost. Some people also express concern about the possible environmental or worker safety impacts of operating irradiation facilities. Others have stated that irradiation will be used as a substitute for sanitary meat-production practices.

FDA has carefully evaluated these and other possible concerns, and has found no adverse impacts that would be of significance. FDA has reviewed a large body of scientific data relevant to the chemical changes resulting from irradiation. FDA's environmental review has taken into account the close regulation, by the Nuclear Regulatory Commission, of facilities using radioactive materials as well as the regulation of worker safety by the Occupational Safety and Health Administration. Good sanitary practices are always important, for quality as well as safety, and will continue to be essential to meat production.

How does irradiation compare to other types of food-sanitation technologies? Does its sanitizing effect last longer than other technologies?

Two factors can play a role in reducing the occurrence of harmful organisms in foods; factors that reduce numbers of microorganisms and factors that prevent further growth. Irradiation, like thermal processing, is quite effective at reducing the number of microorganisms but leaves no residual effect that can prevent later growth of remaining, viable organisms. Thus, its effect can be considered only in light of other, complementary factors such the number of microorganisms before irradiation, the temperature of storage, and the adequacy of controls to prevent recontamination.

Is FDA placing any restrictions on the use of irradiation for meat?

The petition limited the maximum amount of ionizing radiation to be used for the treatment of meat: 4.5 kGy for refrigerated product, and 7.0 kGy for frozen product. The kGy (kiloGray) is a unit of measurement for ionizing radiation. These limits are in the final rule.

How cost-effective is irradiation compared with other food-sanitation technologies?

FDA has not attempted to evaluate costs. Under the food additive provisions of the Food, Drug, and Cosmetic Act, the cost of a technology and its potential benefit to the consumer are not criteria to be considered in permitting use. FDA is required to base its approval decisions strictly on safety considerations.

Does FDA's decision mean that all meats will be irradiated?

FDA's decision does not require irradiation but simply permits it. The extent to which meat will be irradiated will depend on decisions made by the industry and consumers. FDA has not attempted to make market analyses of this technology because it would not affect its decision.

Should consumers handle irradiated meats the same way that they handle non-irradiated meats? For example, can irradiated meat be held longer at refrigeration temperatures before

being cooked or frozen? Can irradiated meat be held longer at freezer temperatures before being cooked? Is there anything different about cooking irradiated meat?

All meats, irradiated or not, should be handled carefully, and stored under refrigeration or freezer temperatures. Just because meat has been irradiated, it is not safe to leave it sitting for prolonged time at room temperature.

Irradiation will delay the spoilage caused by bacteria but food can also spoil due causes that irradiation will not prevent, such as enzyme degradation or rancidity from reactions with air. Because the numbers of spoilage organisms would be reduced, irradiated meats should have a longer shelf life than nonirradiated meats at refrigerated temperatures. Frozen meats tend to degrade for reasons other than growth of microorganisms, and irradiation is not be expected to prolong shelf life.

Cooking meat that has been irradiated is no different than cooking non-irradiated meat.

Are there environmental issues raised by irradiation of meat and other foods? For example, how are radioactive wastes from food-irradiation facilities handled?

Radiation facilities do not produce radioactive waste. Rather, radioactive material used will become less radioactive with time. Generally, radioactive sources that become too weak for some commercial purposes will be used where less radiation intensity is needed or returned to the supplier.

How did FDA handle the environmental issues raised by food irradiation?

FDA examines the potential environmental impact of each of its actions. In this case, FDA notes that a radiation facility that treats food must comply with all other requirements for operation of that facility and that treating food does not present any additional environmental issue. Radiation processing with radioactive sources constitutes an industry closely regulated by the Nuclear Regulatory Commission. FDA concluded that adequate controls exist to prevent any significant adverse environmental impacts.

Is it possible to irradiate food without using radioactive materials?

Yes. Radiation produced by electron accelerators or X-ray generators has the same effect as radiation from radioactive materials. However, food container sizes must be adjusted for different types of radiation because accelerated electrons can't penetrate food more than a few inches, while radiation from radioactive materials is more penetrating and can be used with containers a few feet thick.