# OMRI's Comments on Ionizing Radiation and Organic Food in the December 1997 Proposed National Organic Program Rule


## ***Executive Summary***

Ionizing radiation, or irradiation, can be used to control microbial contaminants, pathogens, parasites, and pests in food. While there has been growing interest in this technique, it is still not widely adopted. Despite a number of potential benefits, irradiation has a number of limitations that prevent its acceptance in organic food handling. Organic certifiers, processors, handlers, farmers, and consumers have traditionally not considered irradiation compatible with organic standards. Familiar, well-established methods besides irradiation of food handling appear effective in reducing microbiological risk in organic foods. These techniques provide consumers with safe food that is handled in a way that is consistent with organic principles. OMRI recommends that the USDA prohibit ionizing radiation in food labeled as organic.


## Background

Ionizing radiation is a technique of food preservation first tried shortly after the discovery of radioactivity, and has been the subject of much research and development by the food industry over the past 50 years. The process is simple: food is exposed to a source of ionizing radiation. While electron beams from an accelerator can be one source, most commercial facilities use radioactive isotopes that emit gamma rays (IAEA, 1997). These rays irreparably damage the genetic material in living cells. Even though an extremely small percentage of chemical bonds are broken when a food is irradiated, the effect can be dramatic. For example, breaking bonds in deoxyribose nucleic acid (DNA) results in the loss of a cell's ability to replicate.

The radioactive isotopes most often used in food handling are Cobalt 60 ($^{60}$Co) and Cesium 137 ($^{137}$Cs). These isotopes produce gamma rays. Radiation dosage is measured in Grays (Gys) where one gray equals one joule per kilogram. A kiloGray (kGy) is equal to 1,000 Gys. Low doses--under 1 kGy--are used to inhibit sprouting and delay the ripening of fruit. Radiation applied to foods at medium doses--1-10 kGys--kills insects and destroys pathogenic bacteria. Most doses are calibrated to pasteurize--as opposed to sterilize--foods, at the minimum needed to reduce pathogens to a tolerable level. Higher doses--10 to 50 kGys--sterilize foods for a variety of uses, such as for space travel and for immune compromised hospital patients who require bacteria-free food. Medium to high doses are usually lethal to the exposed target organisms.

## Benefits

The primary applications of irradiation in food processing are to pasteurize and sterilize foods, eliminate food borne pathogens, and prolong shelf life. Radiation is highly effective at eliminating a wide range of pathogens. For example, a low dose of radiation can kill 99.9% of *Salmonella* in poultry and an even higher percentage of *Escherichia coli* O157:H7 in ground beef (Murano, 1995). Fungi, protozoa, insects, and helminthic parasites are also effectively inactivated to below infectious levels (Urbain, 1986). The disinfestation of pathogenic *E. coli* O157:H7 has increased recent interest in the technique of irradiation (Wood and Bruhn, 1996).

Irradiation can be used to replace certain chemical fumigants, most notably ethylene oxide, aluminum phosphide, methyl bromide, and sulfur dioxide (see Josephson and Peterson, 1983). Quarantined fruits can meet importation restrictions through irradiation rather than methyl bromide (IAEA, 1989). Irradiation is a replacement for ethylene oxide in spice treatment (Wood and Bruhn, 1996). Irradiation can be used to inhibit or delay ripening and senescence in some fruits. These effects forestall decay in ripe fruit and increase food shelf life.

**Drawbacks and Limitations**

Food exposed to ionizing radiation has a number of effects in addition to the purposes for which it is used. Molecules in foods that absorb energy from ionizing radiation become reactive and form ions or free radicals that react to form chemically stable radiolytic products (Woods and Pikaev, 1994). A relatively small change in the DNA of a bacterial cell can destroy the cell. The radiolytic properties should not be confused with radioactivity. The increased radioactivity of irradiated food is a function of the source and dose (Diehl, 1995). For all practical purposes, the increase in irradiation is considered insignificant (McMurray, 1990). However, the long-term effects of the particular radiolytic properties in food, and on the mutations induced in microorganisms that survive radioactive treatment, remains unknown.

Free radicals are highly reactive compounds, and some have been associated with oncogenicity, mutagenicity, and carcinogenicity. Other types of food preparation also create free radicals--deep-frying and charbroiling for example--and some of these products have been linked to possible cancer-causing agents. A number of radiolytic free radicals are believed to be unique to, or at least more prevalent in, irradiated food (Elias and Cohen, 1977). The catastrophic damage irradiation has on DNA offers several techniques to identify food that has been irradiated (Deeble, et al. 1990). While none of these radiolytic free radicals have been conclusively determined to be carcinogenic, their long-term health effects have not been established (Murray, 1990).

As with any technique, some of the target organisms survive. Viruses and spore-forming bacteria are notably resistant to radiation (Diehl, 1995). Even when the toxin producing organisms are killed, the toxins that they produce are not destroyed (Diehl, 1995). While the risk of some food borne illnesses is decreased, others are increased. The two toxins most likely to increase with irradiation are aflatoxins and botulin.

Aflatoxins are produced by a number of organisms, most notably the bacteria *Aspergillus flavus* and *Aspergillus parsiticus.* Researchers noted that aflatoxin production was stimulated in surviving irradiated *Aspergillus* (Bullerman, Barnhart and Hartung, 1973). The result has been reproduced a number of times since then (summarized in Murray, 1990: 118-127).

Botulin is the toxin associated with the food poisoning botulism. It is produced by the aggressive, irradiation-resistant *Clostridium botulinum.* Several incidents and studies have indicated that irradiated seafood has a higher risk of botulism than non-irradiated seafood (Summarized in Diehl, 1995: 226-27 and Murray, 1990: 203-205).

A number of irradiated foods have very specific and demanding packaging requirements. The sterilization of food denatures enzymes and destroys non-pathogenic organisms that occupy niches that pathogens would otherwise control. Once irradiated, many highly perishable foods must be immediately packaged in aseptic vacuum packaging or risk reinfection. A number of secondary contaminants resulting from irradiation have been identified (Murray, 1990). While these are not always pathogenic, they can impart qualitative differences that reduce the palatability of food (Urbain, 1986). This is of particular concern for meat, dairy, seafood, and soft fruit. For example, soft fruits, such as strawberries, have been shown to be susceptible to post-harvest reinfection at low doses. Higher doses are more effective at preventing reinfection, but result in qualitative differences that are not acceptable to consumers, particularly softening. Therefore, to be effective and marketable, irradiated strawberries must be packaged with polyethylene film (Urbain, 1986). Packaged food is often irradiated, which requires that the packaging be suitable for irradiation (21 CFR 179.5).

Organisms may be exposed to sublethal doses of irradiation and still suffer damage to their DNA. Because ionizing radiation is a strong mutagen, surviving organisms are likely to be mutants. These mutant microorganisms might evolve to be virulent, radiation resistant pathogens (Murray, 1990).

Studies have demonstrated an increase in the incidence of polyploidy--the production of more than the usual number of chromosomes--in subjects fed irradiated wheat. These results have been replicated numerous times (Murray, 1990). Although these findings are disputed (Diehl, 1995), further study and replication appears to be needed, and the results better understood.

Rather than replacing chemical additives as is often claimed, ionizing radiation can actually use more processing aids and preservatives than similar non-irradiated foods (Webb, Lang and Tucker, 1987). For example, one source recommends that meat treated with irradiation be dipped in a solution of a condensed phosphate, such as sodium phosphate, to prevent bleeding and discoloration (Urbain, 1986). Others suggest that a number of irradiated foods be treated with synthetic anti-oxidants like B.H.A. and B.H.T. to scavenge the free radicals created by the process (see Josephson and Peterson, 1983).

Irradiation degrades the nutrient constituents of most foods. Vitamins are particularly sensitive to the effects of ionizing radiation (Thayer, Fox, and Lakritz, 1991). Vitamins C and E are particularly susceptible, given their role in destroying free radicals. The creation of free radicals in the irradiation process accelerates the degradation of these vitamins. Vitamin E was found to be the most sensitive of all fat-soluble vitamins to gamma irradiation (Knapp and Tappel, 1961). B-vitamins have fewer losses, but these are still measurable (Wood and Bruhn, 1996). Other nutrients lost through irradiation are proteins and essential amino acids (Murray, 1990).

Although there are other techniques that produce vitamin, protein, enzyme, and amino acid losses (Wood and Bruhn, 1996), these techniques are more familiar to consumers. Irradiated foods that are sold ready-to-eat will have a lower vitamin content than comparable fresh foods. Those that are subject to further processing will further lose nutritional value. In either case, irradiated food will have lower nutritional value than non-irradiated food, all other things being equal.

Finally, irradiation changes the organoleptic properties of most foods. Flavor, odor, texture, and color are all modified by irradiation (Murray, 1990; Urbain, 1986). While some are considered improvements (Wood and Bruhn, 1996), many of these characteristics are considered by consumers to be sensory defects (Webb, Lang and Tucker, 1987; Murray, 1990). Dairy products will develop off-flavors at doses as low as 500 Gy. A number of foods become inedible at doses treated at the levels necessary to eliminate most microbiological pathogens (Murray, 1990). Soft fruits become unacceptably soft at doses needed to sterilize them (Urbain, 1986). The phenomenon of luminescence--the glowing of substances treated with irradiation--is also well documented (Sanderson, 1990).

## Irradiation and Organic Standards

At present, no organic certifier in the United States allows irradiated food to be labeled as organic. The International Federation of Organic Agriculture Movements (IFOAM) Basic Standards prohibit the use of ionizing radiation by handlers certified by certifiers that it accredits (IFOAM, 1997). Organic processors and handlers have shown little interest in food irradiation, therefore there has been little discussion of the issue by the organic community. Most of the debate over the technology has taken place in other arenas.

## Other Agencies

The Food and Drug Administration, following a 1958 amendment to the Food, Drug and Cosmetic Act, considers radiation to be a food additive. To quote from the act:

> "The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use) . . . ."

Most of the research and development of ionizing radiation has taken place in the Department of Defense, primarily within the US Army. The Army sought to end the program because:

- Other techniques improved preservation over irradiation;
- Irradiation did not preserve the wholesomeness of the food; and
- The cost of safely operating food irradiation facilities (U.S. GAO, 1978).

An investigation of the government contractor, Industrial Bio-Test (IBT), who provided most of the food safety data on which the FDA granted the Army's permit for irradiation, was found to falsify data and provide fraudulent results (GAO, 1978). The Environmental Protection Agency later investigated the contractor. IBT officials were subsequently convicted of fraud for falsifying data used to register pesticides (Marshall, 1983). Many studies conducted by other researchers suffered from methodological problems. Almost one-third of the tests submitted to FDA regarding the safety of irradiated food were rejected (Diehl, 1995). When methodologically flawed and rejected studies are factored out, nearly half of the remaining studies showed adverse effects (Rebus, 1990).

## OFPA and Congressional Intent

Ionizing radiation is not mentioned in OFPA. However, this cannot necessarily be construed as consent. Because it is considered a food additive, its use is constrained by the requirement that the food be handled without synthetic chemicals [7 U.S.C. 6504(1)]. The bombardment of $^{59}$Co with gamma rays to produce $^{60}$Co is not a natural process. The change at the nuclear level is arguably a chemical change. Therefore, irradiation with enriched isotopes is arguably a synthetic process. Even if one were to refine naturally occurring isotopes, the process would remain suspect under the structure of OFPA. The OFPA definition of 'processing' does not include irradiation in the list of processes. Because it is still relatively uncommon, and because of the special licensing and permitting that goes with operating an irradiation facility, it is difficult to consider irradiation part of ordinary food manufacturing.

When irradiation is evaluated against the 2119(m) criteria as an additive in OFPA:

1) *Interactions.* As mentioned above, ionizing radiation creates free radicals in foods. Most official sources report no negative interactions; many researchers regard the evidence of detrimental effects as inconclusive.

2) *Toxicity and Persistence.* Medium and high doses are dangerous to exposed individuals. Safety precautions can reduce the risk of exposure. The half-life of $^{60}$Co is 5.3 years; the half-life of $^{137}$Cs is 30 years (Diehl, 1995).

3) *Environmental Contamination.* $^{60}Co$ is produced by the bombardment of $^{59}Co$ pellets in nuclear power plants. The source for $^{137}Cs$ is spent fuel rods from nuclear power plants. The need to remove and reprocess spent radionuclide sources requires transportation and handling. These steps have the greatest potential risk for human exposure to gamma radiation. $^{60}Co$ decays back to $^{59}Co$, which is then reprocessed back into $^{60}Co$. $^{137}Cs$ decays to stable $^{137}Ba$ (Barium). The $^{137}Cs$ is separated from the $^{137}Ba$ and is stored as cesium chloride (CsCl). Because CsCl is water soluble, it has the potential to leak and contaminate the environment. The source needs to be replaced when the radioactivity is between 6% and 12% of the original level (IAEA, 1997). This means that there is some potential for exposure to radioactive waste.

4) *Effects on Human Health.* The lethal dose for humans is rated at 4 kGy (Murray, 1990). Therefore, irradiation facilities cannot have humans present in the chamber where food is exposed to the radioactive material. Facilities are engineered and constructed with extensive safety systems to prevent human exposure. In spite of safety precautions, there have been major and even fatal accidents at irradiation facilities (IAEA, 1997). The effects on humans who eat irradiated food are less clear. There is evidence that free radicals in the food can have adverse health effects, and that the food is less wholesome. This evidence is disputed by a number of authorities. Both studies showing evidence of adverse effects and those showing no adverse effects have been labeled methodologically flawed.

5) *Effects on the Agroecosystem.* The radioisotopes and the radioactive waste are generally not released into the agroecosystem.

6) *Alternatives.* Sanitation, quality control, worker hygiene, refrigeration, freezing, hot water dips, ozone, hydrogen peroxide, controlled atmosphere, carbon dioxide, timing of harvest (pick-to-order), local marketing, consumer education, and beneficial organisms such as *Pseudomonas syringae* and parasitic wasps.

7) *Compatibility with Sustainable Agriculture.* Food irradiation has generally been considered not consistent with the primary thesis of organic food definition, that is, food be grown with naturally occurring substances and minimally processed to the extent possible. In this sense, irradiation is no more or less compatible with organic handling than synthetic preservatives, chemical fumigation, and synthetic fungicides. Irradiation of food had the distinction of being rated the least compatible with organic food processing of 323 processes in a survey of companies in the organic trade (Raj, 1991). This was confirmed by polls taken by the Organic Trade Association at meetings in Washington, DC and Newark, CA.

**NOSB Recommendation**

The NOSB recommended a prohibition of ionizing (gamma) radiation in Addendum #7, "Good Organic Manufacturing Practices," adopted April 25, 1995 in Orlando, FL. This is found on lines 135-139 on page 5 of the addendum and reads:

II(3)(c) Ionizing Radiation [refer to 21 CFR Part 179.26]

> "Ionizing radiation for the purpose of killing insects or microorganisms in food (21 CFR 179.26) may not be used in the handling of organic food. Use of radiation (X-rays) for the inspection of organic food is allowed (21 CFR 179.21)."

**NOP Proposed Rule**

The Rule opens for discussion the use of irradiation:

> "As previously discussed in regard to the use of raw manure in organic crop production (section 205.7 of subpart B), there has been an increase in the incidence of food borne illness caused by certain pathogens. FDA currently permits the application of ionizing radiation as a sanitation or preservation treatment for a wide range of agricultural products. Additionally, a request to permit the use of ionizing radiation on red meat products was recently approved by FDA. The NOSB has recommended to the Secretary that the practice of ionizing radiation should not be allowed in organic handling, and most existing organic certification programs that we have reviewed prohibit its use.
>
> "Public comment is invited with respect to the compatibility of the use of ionizing radiation with a system of organic farming and handling. The USDA also invites comments on whether there are effective alternatives to ionizing radiation, such as sanitary practices, heat pasteurization and incidental additives, that are compatible with a system of organic farming and handling, and, if so, how they are compatible. Additionally, we are soliciting comment as to whether the use of ionizing radiation is considered an essential standard industry practice, or good manufacturing practice, in the processing of any agricultural product: for example, in the sanitary handling of herbs and spices." (Docket Number: TMD-94-00-2; 62 *Fed. Reg.* 65884)

**Effective and Acceptable Organic Handling**

Consumers expect organic food to be fresh, safe, and minimally processed. Irradiation is incompatible with organic production for the same reasons that fungicides, fumigants, artificial ripening agents, and synthetic preservatives are incompatible: these substances are used to modify the natural processes of ripening and decay. Organic processors and handlers are sensitive to the demands of organic consumers. Consumers are concerned that foods that have been irradiated will be marketed as fresh, when they are actually much older than they appear (Gibbs, 1993).

Food irradiation does not eliminate the need for proper handling (Wood and Bruhn, 1996). Nonetheless, irradiation has been used to reduce unacceptably high levels of microbiological contamination in foods that were later represented as not treated with irradiation (Sanderson, 1990). Irradiation of contaminated food after processing is not considered a Good Manufacturing Practice and is in violation of international norms.

Organic handlers also understand that irradiation is expensive and consider other techniques to be more cost-effective. Many of the alternative techniques are specific to the commodity system and critical control point. Examples include preventive sanitation, hot water treatment, removal of free moisture and field heat, maintenance of optimal storage temperature and humidity, improved quality control, and worker hygiene. Some technological advances, such as improved assays for pathogens, offer alternative means to protect public health without changing processing or handling techniques. Given a limited budget for implementing a Hazard Analysis Critical Control Point (HACCP) program, most organic processors would prefer to spend the money on techniques they consider to be more cost-effective, even if irradiation was accepted both by organic certifiers and consumers.

Food irradiation can reduce spoilage and improve shelf life, but it is not a substitute for hygiene as a preventive measure for food poisoning. Other proven techniques include refrigeration, freezing, hot water dips, ozone, hydrogen peroxide, controlled atmosphere, carbon dioxide, and beneficial organisms such as *Pseudomonas syringae* and parasitic wasps. To specifically address the question raised by NOP, the prohibition of irradiation does not necessarily require the allowance of synthetic incidental additives. Any specific synthetic additive allowed for use in organic production should either be on the National List or meet the NOSB's recommended criteria for incidental additives. The Proposed Rule's definition of incidental additive is too broad.

## Conclusion

Organic food must meet the safety requirements for all food. Ionizing radiation is one of many tools available to control and eliminate microbial pathogens, but this technology has not traditionally been used in organic processing and handling. While irradiation can make contaminated food safer by killing harmful microorganisms, the treatment also changes the chemical structure and some of the food's constituents in ways that change the characteristics of food. There is also a well-founded concern that the technology might introduce new hazards, even as it mitigates old ones.

Organic food can meet safety requirements without ionizing radiation. Other, more established good manufacturing practices are more compatible with organic handling. Advances in other techniques related to the widespread adoption of HACCP have improved food safety. The application of ionizing radiation presents unresolved questions regarding consumer choice, food safety, and environmental quality.

The NOSB should be asked its opinion on the irradiation of allowed non-organic ingredients. If government regulations mandate the irradiation of certain foods, either as an alternative to mandatory chemical treatment or outright, then the organic industry will face the choice between having irradiated food labeled as organic or not having those foods available in the organic market niche. OMRI's recommendation is that the NOSB should be consulted for their preferred course in that choice, and that their expertise and representation of the organic community be given great weight.

According to all NOSB recommendations and all current certification standards, ionizing radiation is prohibited in organic handling. OMRI recognizes that OFPA is not clear on the issue. Pursuant to 7 U.S.C. 6512, OMRI urges the USDA to explicitly state whether or not ionizing radiation is consistent with organic certification. OMRI further respectfully requests the Secretary to rule that ionizing radiation is *not* consistent with organic principles and standards. The USDA should adopt the NOSB recommendation and the existing standard of all US certifiers and maintain a prohibition on the use of ionizing radiation for food labeled as organic.

OMRI asks that 7 CFR 205.17(b)(4) of the proposed rule be revised to include the following language:

**205.17(b) Prohibited . . .**
(4) Treatment with ionizing radiation.

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