Testimony by Dennis G. Olson Subcommittee on Oversight and Investigations Committee on Energy and Commerce U.S. House of Representatives

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Mr. Chairman, I would like to thank the committee for inviting me to offer my views on food irradiation. My career has been devoted to this subject through teaching, research and commercial applications. In 1993, I commissioned the first electron-beam food irradiation facility at Iowa State University and developed an extensive program in food irradiation research and education in cooperation with many other universities.

Irradiation can be a powerful weapon in the nation's food safety arsenal. It destroys pathogenic bacteria without changing the nature of the treated food. The effect is similar to pasteurization, in that food is made safer, while maintaining the taste and appearance of the untreated product. Of course, the absence of heat means that, in comparison with pasteurization, irradiation can be applied to a much wider range of fresh or ready to eat foods. Food irradiation cannot make food radioactive. The equipment used for food irradiation does not have sufficient energy to cause radioactivity in any treated material, including food, regardless of the amount of irradiation absorbed.

Irradiation is not a new technology, and food irradiation is not a new topic, even in these halls. In June 1965, following more than twenty years of research by the Army, the US Army Surgeon General testified before Congress and concluded that "foods irradiated up to an absorbed dose of 5.6 Mrad (56 kGy) with a cobalt-60 source of gamma radiation or with electrons with energies up to 10 million electron volts (MeV) have been found to be wholesome, i.e. safe and nutritionally adequate.(1)" The Surgeon General, in that report more than 40 years ago, concluded that irradiated food is safe regardless of the dose (2). Since then, decades of increasingly sophisticated research have affirmed that conclusion. Now, more than forty years later, I welcome the opportunity to repeat that message. Irradiated food is safe.

In recent decades, irradiation has been increasingly adopted to sterilize medical products, and is now considered state of the art in medical sterilization. That same evolution should have occurred in food irradiation, and that it did not happen is quite literally a tragedy. The millions of pounds of contaminated ground beef, lettuce and spinach that have been recalled in the last eighteen months, and the sickness and death that accompanied those recalls, would have been prevented if those products had been irradiated.

The companies and the trade groups involved in these recalls, many of whom have testified before this Subcommittee, have all promised to do better. But they have also said, in a variety of ways, that despite their best efforts there is no "Kill Step" that will insure their customers do not become sick in the future. Those assertions are simply not true. The pathogens responsible for these recalls, E. coli O157:H7, Salmonella and

Listeria monocytogenes, can be killed by proven, available and safe technology. Food irradiation is that "Kill Step."

I am convinced that food irradiation should be, and ultimately will be, broadly used in the food industry. As that occurs, food irradiation will become one of the Pillars of Public Health, along with chlorination of water, pasteurization of milk and juices, and vaccination, in the prevention of illness. I urge Congress to advance the application of irradiation in the food industry. To that end, approved uses of irradiation need to be expanded, regulatory agencies and public health professionals need to actively engage with consumers to educate them about the benefits of the technology. Labeling requirements, if needed, should be informative not alarming. Food processors need to be encouraged to adopt irradiation, or alternative food safety interventions that guarantee a comparable reduction in risk.

The first step needs to be an immediate increase in the scope of governmental approved uses for food irradiation. Of the products involved in the recent recalls, only ground beef has adequate approval from FDA and USDA. Irradiated ground beef is currently available in the marketplace, but in limited amounts. None of the major ground beef producers market an irradiated product.

With regard to leafy greens, which include spinach and bagged salads, the FDA allows irradiation for insect control and shelf-life extension, but does not allow it to be used for pathogen reduction. In order to allow irradiation for pathogen reduction in leafy greens, the FDA needs to approve both the use and the increased dose necessary for effective pathogen control in these products. That approval should have been granted years ago. In late 1999, a petition to allow irradiation for pathogen reduction in fruits and vegetables and other ready to eat foods (FAP 9M4697) was submitted to FDA. Eight years later, that petition is still pending. Two petitions submitted to FDA by USDA, its sister agency, also remain "pending" after more than eight years (FAP 0M4695 and FAP 9M4696). Yet, these petitions are being considered under the agency's "expedited" review process.

The FDA's review responsibility with regard to irradiation petitions is to evaluate safety. Safety in this context involves assessment of microbiological risk, potential toxicity and nutritional adequacy. Although it sounds complicated, after decades of research this evaluation should be a simple task. There is no longer any question about the safety of irradiated foods. In fact the kind of case by case review that the FDA requires has been irrelevant and unnecessary for more than a quarter century.

In 1980, the World Health Organization published a report summarizing all of the research to that date (3), and concluded that any food, even if irradiated to a moderately high dose, would be wholesome. In other words, safe and nutritionally adequate. The same conclusion reached by the US Army Surgeon General fifteen years earlier. The WHO report further concluded that further research on the safety of food irradiation at moderately high doses was unnecessary.

In response to the WHO report, the Codex General Standard for Irradiated Food was adopted in 1983. Those standards provided that irradiation of any food up to an average dose of 10 kiloGray (kGy) presented no concern. The FDA did not adopt the Codex recommendations.

In 1999, the World Health Organization issued a subsequent report on high dose irradiation and concluded there is no irradiation dose where foods become unsafe (4). In 2003, the Codex Alimentarius Commission, which is the highest international body on food standards, revised its 1983 Standard to lift all restrictions on food categories or dose limits for irradiated foods. The Codex standard does provide that doses above 10 kGy should only be used when needed to achieve a technological purpose. There are now 15 countries that permit the irradiation of any food, and several allow irradiation at any dose. The U.S. is not one of them. The limited approvals of irradiation in the U.S. has continued despite the support of the American Medical Association, American Dietetic Association, American Veterinary Medical Association, Center for Disease and Protection, Public Health Service, Council of Science and Technology, Institute of Food Technologists, National Association of State Departments of Agriculture and others recognizing the safety and benefits of food irradiation (5).

The FDA apparently believes that the 1999 WHO report considered all of the studies the FDA considers relevant (6), and has expressed no disagreement with the conclusions in that report. Nonetheless, FDA continues its outdated petition by petition review. Perhaps, in light of the evidence outlined above, the time has come to consider whether the classification and regulation of irradiation as a food additive should be changed.

When food processors discuss irradiation they often claim either that they have not studied its use, or have determined that it will damage the product, making it unacceptable in the marketplace. I believe the quality issue is not a real issue, but in any case it should not be a regulatory concern. The marketplace will ultimately decide if quality is compromised by irradiation. For my part, I have confidence in the capacity of the food industry to develop packaging, product configuration, processing temperature and irradiation dose to offer high quality and safe irradiated foods.

If there is a quality hurdle, it is a very low one. Several irradiated food products, and the non-irradiated controls, are available today for your evaluation. These products were purchased off the shelf, and irradiated in their retail packages without any intervention to improve quality. I believe they demonstrate that quality does not have to be sacrificed in an irradiated product.

Adoption of irradiation technology in the food industry is impeded by lack of timely and adequate FDA approvals, warning-style labeling requirements, the lack of engagement of public health officials to promote the safety of irradiated foods to consumers, and of course, the food industry's desire to avoid increased cost.

The cost of irradiation is a valid concern. In addition, there are only a few irradiation facilities in the U. S. currently capable of irradiating food in commercial volumes. The limited number of irradiation facilities can mean high transportation costs, but that is not unusual to a developing technology. Increased demand will lead to more, better located, irradiation facilities. Nonetheless, even with the current limited capacity, it should cost only cents per pound, including transportation. The offsetting benefits of irradiation are no recalls, no illnesses, no deaths and avoided litigation awards.

Mr. Chairman, thank you again for inviting me to testify on the application of this important pillar of public health technology; food irradiation. I solicit your help to get all foods approved for irradiation and to and eliminate the unwarranted warning-type label requirements. We should not accept the fact that a number of our citizens will get sick, be hospitalized or die because the government has not allowed the food industry to adopt food irradiation for all foods to prevent those catastrophes.

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(1) Radiation Processing of Foods. Hearings before the Congress of the United States, 9 and 10 June, 1965. Washington, DC, US Government Printing Office, 1965, pp. 105--106.

(2) Wholesomeness of irradiated food. Report of a Joint FAO/IAEA/WHO Expert Committee. Geneva, World Health Organization, 1981 (WHO Technical Report Series, No. 659).

(3) A dose of 56 kGy is more than 10 times the maximum dose currently approved for fresh meat, and higher than the dose approved for sterilizing foods to be used by NASA in the space program. [21CFR 179.26(b)(8)]

Joint FAO/IAEA/WHO Study Group on High-Dose Irradiation (Wholesomeness of Food Irradiated with Doses above 10 kGy) (1997: Geneva, Switzerland)
Wholesomeness of food irradiated with doses above 10 kGy: report of a Joint FAO/IAEA/WHO Study Group - WHO technical report series: 890

(5) Food Irradiation: Available Research Indicates that Benefits Outweigh Risks. GAO Report (GAO/RCED-00-217) to the Committee on Commerce, Sub-Committee on Oversight and Investigations, U.S. House of Representatives, August, 2000.

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Summary Points

- 1. Food irradiation cannot make food radioactive.
- 2. Irradiated food is safe.
- 3. Food irradiation can be the "Kill Step" to prevent pathogens from causing illness.
- 4. When widely adopted, irradiation will be a Pillar of Public Health along with chlorination, pasteurization and vaccination in preventing illness.
- 5. More FDA approvals to irradiate all foods are needed immediately.
- 6. Quality of irradiated foods is not a regulatory concern and industry can overcome any quality issues.
- 7. Labeling of irradiated foods, if needed, should be informative not alarming.
- 8. Cost to irradiated foods is cents per pound and will lower as more facilities are built.
- 9. Expanded use of irradiation for food will decrease illness.