*Nuclear Technology Enhances Freshness*

# Food Irradiation Processing Struggles for Global Acceptance

"Irradiation of any food commodity at an overall average dose of 10 kGy (1,000 krads) presents no toxicologic hazard and does not pose specific microbiologic or nutritional problems. Ultimately, the international trade in irradiated food will become just as acceptable as the trade in irradiated medical supplies."

Bombarding food with electron beams, gamma rays, or x-rays has impressive potential in extending the food harvest and alleviating world hunger.

To combat the loss of food from spoilage and pests, which amounts to 25 percent of global production, 21 countries have approved radiation as a means of preserving 80 different foods. Last year, an estimated 35,000 tons of food underwent the process.

"Continued international collaboration is essential for successfully paving the way to international trade," said W.J. DeWet, manager of the chemistry department at the Nuclear Development Corp. in Pretoria, South Africa.

Speaking at the International Symposium on Food Irradiation Processing last month in Washington, DC, Dr. DeWet said that consumer acceptance, during a market study of irradiated potatoes, mangoes, papayas, and strawberries, reached 90 percent in Pretoria and Johannesburg supermarkets. "The commercial application of food irradiation in South Africa should contribute to international acceptance," he added.

Sponsored by the International Atomic Energy Agency (IAEA) and the Food and Agricultural Organization (FAO), the week-long conference attracted close to 300 representatives from 38 countries.

"It is hoped that both the Codex General Standard for Irradiated Foods, adopted by the Codex Alimentarius Commission in 1983, and the work of the International Consultative Group on Food Irradiation, will promote the diminution of the disharmony between countries in their acceptance of irradiated foods," said J. Farkus, of the Central Food Research Institute in Budapest, Hungary.

The Codex General Standard was developed by a group of experts convened by the FAO, the IAEA, and the World Health Organization (WHO), and reviewed by 122 governments.

The Codex Alimentarius Commission sets standards and is the vehicle for international exchange of scientific data. The International Consultative Group on Food Irradiation, established in 1983, is composed of 15 countries (Argentina, Bangladesh, Canada, Egypt, France, Hungary, Iraq, Israel, Mexico, The Netherlands, the Philippines, Syria, Thailand, Turkey, and West Germany), and evaluates global developments in the transfer of this technology to the food industry.

Dr. Farkus noted that the Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food concluded in November 1980 that irradiation of any food commodity up to an overall average dose of 10 kGy (1,000 krads) presents no toxicologic hazard, and does not pose specific microbiologic or nutritional problems. "It is confidently expected," he said, "that within the next few years many countries will allow the process, and ultimately the international trade in irradiated food will become just as acceptable as the trade in irradiated medical supplies."

The United States has also studied the technology. According to Greg Mitchell, editor of *Nuclear Times* magazine, the Army requested a study in 1943 on irradiated food for soldiers. Massachusetts Institute of Technology concluded after four years of research that the procedure was safe.

**Most thoroughly tested method**

Since then, the United States has spent $50 million on further studies that indicated the same finding, said Mr. Mitchell. The U.S. Atomic Energy Commission said in 1970 that the irradiation process "has been more thoroughly tested than any other method of food preservation."

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Only two facilities in the European region, to Dr. Farkus's knowledge, are used solely for food treatment on a commercial basis—the cobalt-60 "gammir II" batch irradiator of the Mediris plant in Fleurus, Belgium, and the grain disinfestation plant at the Odessa Port Elevator RDU in the Soviet Union, which uses two electron accelerators. Many more facilities, however, are in the experimental and planning stages.

Xu Zhi-Cheng, of the Shanghai Institute of Nuclear Research, described the technical design of the Shanghai Irradiation Center, scheduled to start operations this year.

The initial loading will be a 200,000 Ci cobalt-60 source, stored in water, and eventually increased to 500,000 Ci. He expects a productivity of 20 tons of potatoes per hour, a ray utilization ratio of 18.6 percent and a radiation uniformity of 1.6.

The Shanghai Institute has also studied radiation effects on apples, onions, garlic, longans, red bayberries, oranges, cauliflower, carrots, green peppers, and winter bamboo shoots with positive results. Animal feeding tests showed no carcinogenic mutations or other harmful effects from irradiated diets, said Dr. Xu.

Radiation kills bacteria by genetic damage, and curbs ripening by slowing the rate of mitosis. An onion, for example, remains fresh for a year after exposure to gamma rays. The technology can also minimize changes in color, flavor, texture, and nutritional value, said Mr. Mitchell, and is "superior to canning and freezing."

Researchers continue to study optimal dosimetries for specific foods and packaging, as well as the effects of radiation on molecular structure, enzyme activity, fungal or bacterial growth, and baking properties.

Scientific papers presented at the symposium showed the results of radiation experiments on wheat in Iraq, dried Rahu fish in Pakistan, spices in India, shrimp in The Netherlands, anchovies in Turkey, potatoes in Poland, clams in Massachusetts, and papayas in Hawaii.

### Rules and regulations

Unconditional and provisional clearances for food irradiation vary dramatically between countries.

The Netherlands leads the world with 17 food applications ranging from froglegs to batter mix. Chile irradiates 13 items, Bangladesh uses the technique for 12 products, and South Africa "radurises" ten foods.

The United States limits irradiation to potatoes, wheat, and spices on a restricted basis. Thailand only does onions, and Argentina, Denmark, Japan, and the Philippines allow just potatoes to be exposed.

Chemists from South Africa's Nuclear Development Corp. offered their marketing plan at the symposium as a model for gaining the technology's acceptance with government regulators, the food industry, and consumers. Their strategy extensively involved scientists in providing relevant data to the government, and in conducting a continual campaign of public education.

To educate scientists and health officials from other countries, the International Facility for Food Irradiation Technology in The Netherlands offers training courses.

The U.S. Food and Drug Administration announced proposed food irradiation rules last year (*Federal Register*, Feb. 14, 1984).

Congress will consider a redrafted food irradiation bill this year. Proposed source material includes cesium-167 capsules stored at the U.S. Dept. of Energy's Hanford facility in Washington State.

The bill proposes a change in the Food, Drug and Cosmetic Act that would classify irradiation as a process instead of an additive. It also sets radiation limits at 100 krads, one-tenth of the international standard.

One major obstacle to the bill's passage is a study by Raltech Scientific Services. After feeding more than 300,000 pounds of irradiated chicken to mice, hamsters, rats, rabbits, and beagles over several generations, four out of 104 mice in one group devel-

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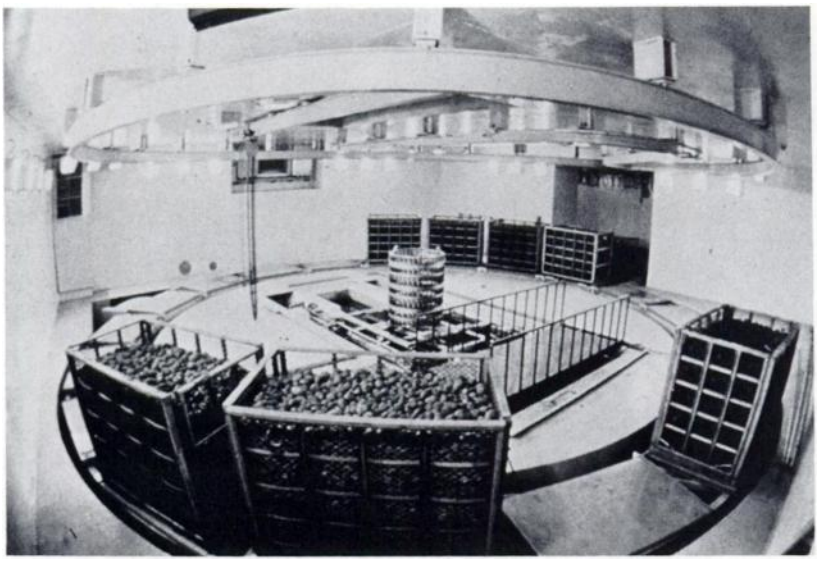

*A shipment of potatoes in Japan undergoing irradiation revolves around the cobalt-60 source at center.* **(Courtesy of the International Atomic Energy Agency)**

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oped benign testicular lesions, compared to only one mouse out of 115 in a control group.

Another snag is the discovery of unique radiolytic products (URPs). They are unusual molecules, altered forms of amino and fatty acids, for example, that are never found in unexposed food. Although they are not necessarily harmful, scientists have not yet identified all URPs or shown that they cause no ill effects.

Since the U.S. Environmental Protection Agency banned ethylene dibromide last September, though, irradiation is a more viable alternative.

**Misleading labeling?**

Officials cannot agree on a labeling requirement. The FDA has dropped its labeling proposal for retail packages because irradiated foods "have already been shown to be safe."

A label connotes a warning, some regulators say, which is misleading—especially when food treated with potentially more harmful pesticides does not require a label.

Although the public is wary of radiation, other officials feel that the technology is doomed unless consumers are fully informed.

The Netherlands requires a "RADURA" symbol, composed of a stylized flower in a solar disc, on all packages. In South Africa, foods are labeled with this emblem on the wholesale level, and retail labels are optional

A poll conducted for the Canadian Dept. of Fisheries and Oceans indicated that labels are necessary. Test-marketed consumers preferred "freshness extended by irradiation" and "ionized fresh" over "irradiated" and "treated with ionizing radiation."

Although the process has gained acceptance in some regions, many consumers have yet to learn that irradiated food is not radioactive.

*—Linda E. Ketchum*

# FDA Revamps Drug and Antibiotic Regulations

The U.S. Food and Drug Administration (FDA) has announced its new drug and antibiotic regulations (*Federal Register*, Feb. 22, 1985, pp. 7452–7519).

"The improvements will help applicants prepare and submit higher quality applications, and permit the FDA to review them more efficiently and with fewer delays," according to the agency.

The final regulations take effect on May 23, 1985, although the agency will accept applications under the old regulations until February 24, 1986. The reform effort began in October of 1979, and was accelerated at the request of the President's Task Force on Regulatory Relief.

About 120 comments were reviewed, with input ranging from pharmaceutical manufacturers, trade associations, and consumer groups to health professionals, including some members of The Society of Nuclear Medicine.

"It's a very good start toward improving the review process and making it more efficient," said Capt. William H. Briner, chairman of the Society's Government Relations Committee.

One major change in the regulations, approval of applications based solely on foreign data, may be of particular interest to radiopharmaceutical manufacturers. The agency has increasingly relied upon foreign data in its decisions, and has decided that its "foremost consideration would be the quality of the data submitted, regardless of the country of origin."

To meet various concerns raised about this change, such as medical, genetic, and cultural differences between countries, lack of the FDA's knowledge of foreign investigators and facilities, and the FDA's inability to conduct onsite verification of many foreign studies, the agency specified three criteria to be met in these applications: (a) foreign data must be applicable to the U.S. population and medical practice, (b) clinical investigators must be of recognized competence, and (c) the FDA must be able to validate data through onsite inspection if necessary.

The FDA also recognized, but did not change, the role of outside experts, such as the Radiopharmaceutical Drugs Advisory Committee. The agency denied requests to formally establish a role for these committees in the routine review of applications, and does not permit applicants to utilize advisory committees on demand for review or to resolve scientific disputes.

The agency also did not agree with suggestions to place stricter controls on conflict of interest problems with outside experts. The current guidelines stipulate that advisors will not be barred from serving on a committee where such a problem may arise, but will be excluded from participating in specific matters in which a real or potential conflict of interest exists.

Several Society members participate in the Radiopharmaceutical Drugs Advisory Committee. Under the chairmanship of Barry A. Siegel, MD, director of nuclear medicine at Washington University School of Medicine, this committee has worked constructively with the FDA to gain approval of new indications for widely-used radiopharmaceuticals (see *Newsline*, Mar. 1985, p. 218). ■