Time to Modernize the Law on Food Irradiation

By ACSH Staff — June 24, 2008

The massive outbreaks of *E. coli* 0157:H7 in spinach and lettuce in 2006 caused several deaths and hundreds of illnesses and devastated the produce industry. Since then, the FDA has been under increasing pressure to approve the petition -- submitted in 1999 -- to allow irradiation of ready-to-eat food. Irradiation technology could be used to ensure microbiological safety of fresh produce. Some national TV networks and many popular and scientific articles (including one by this author) demanded that irradiation be used to provide the necessary "kill step" for pathogens in fresh produce.

In March 2008, Dr. S. Sandlof, Director of the FDA Center for Food Safety and Applied Nutrition, testified at a Congressional subcommittee hearing to launch legislation on food safety. Dr. Sandlof stated that the discovery of "furans" in some irradiated food had caused FDA concerns, hence the delay in considering the petition for irradiating ready-to-eat foods. He believed that international organizations were unaware of this compound in their earlier evaluations of the safety of irradiated food. He expected that the FDA's review process would be completed by the end of this fiscal year.

With regard to the "furans" in irradiated produce, which appear to be the FDA's "last straw," it is difficult to comprehend why the FDA has pinpointed this group of compounds (it is not clear whether Dr. Sandlof meant "furan," which is a single compound found in irradiated apple juice as reported earlier by the FDA, or "furans," which is a group of compounds), knowing full well that the quantities detected in some irradiated food were lower than those found in heat-treated foods. The sensitivity of modern analytical instruments would enable us to detect extremely small amounts (ppb levels) of toxic compounds in any foods. Many of these compounds, when tested in purified form, would demonstrate some toxicity to humans.

Among these compounds are benzene, benzopyrenes, acrylamide, and more. It is nonsense for the FDA to consider minute amounts of some compounds (such as furan) in irradiated food while turning a blind eye to the same compound in larger quantities in foods treated by other processes. International organizations (Food and Agriculture Organization of the United Nations [FAO], International Atomic Energy Agency [IAEA], and the World Health Organization [WHO]) that have monitored the safety of irradiated foods since 1960s have been aware of the existence of tetrahydrofuran (not "furans" as indicated by Dr. Sandlof) in irradiated apple juice since 1980. However, the expert committee on the wholesomeness of irradiated foods appointed by the three organizations considered the quantity discovered so minute that it does not raise toxicological concerns.

But no excuse explains the FDA taking more than eight years to consider the petition in favor of food irradiation -- submitted when George W. Bush was still the governor of Texas and Saddam Hussein still ruled Iraq with an iron fist. So much has happened in the past eight years, but the
FDA still appears to be unmoved by the safety and effectiveness of irradiation as a sanitary treatment of fresh produce. In view of the many illnesses and lost lives of people who consumed contaminated produce over the past eight years, the FDA should be asked who is to be held accountable. These tragic incidents could have been prevented had irradiation been approved for sanitizing fresh produce. The Congressional subcommittee should also ask whether it is justified to continue classifying food irradiation as a food additive.

Why it has taken the FDA so long to review the petition on irradiated ready-to-eat foods? Dr. George Pauli, former Director of FDA Pre-Market Approval, notes that the FDA regulates food irradiation based on provisions of the Food Additive Amendment of 1958, which defines a food additive as "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), including any source of radiation intended for any such use."

It is likely that food irradiation was incorporated into the 1958 amendment because of the lack of scientific knowledge on the technology -- especially its safety -- at that time. It should be recalled that 1958 was in the midst of the Cold War and the threat of nuclear war was looming. It was then generally believed that exposing food to _any_ source of radiation would either induce radioactivity or induce new substances in treated food that would be carcinogenic.

Because food irradiation is regulated as a "food additive," the FDA requires scientific evidence to demonstrate the safety of each and every irradiated food, as it would for individual food additives. A petition must be submitted to the FDA for each irradiated food along with data demonstrating its safety. If the same food undergoes any treatment or change in its composition in any way prior to irradiation, a new petition together with the safety data of the new food will have to be submitted to the FDA as if it were a new additive.

The FDA's classification of food irradiation as a food additive has a negative impact worldwide as most, if not all, countries follow the FDA's protocol in regulating this technology. The UK government decided in the early 1990s, however, to approve food irradiation as a food process, and to regulate irradiated foods based on food classes, e.g., fruits, vegetables, cereal grains, poultry, seafood, spices, and seasonings, rather than individual food items. The International Consultative Group on Food Irradiation (ICGFI), an inter-governmental advisory body of FAO, IAEA, and WHO, recommended a model regulation, similar to the one introduced by the UK government, to all other member countries. As a result, in the late 1990s, many countries in Asia and the Pacific, Africa, the Middle East, and Latin America started to regulate food irradiation as a food process based on food classes. Brazil has taken further action -- it regulates food irradiation as a food process regardless of food products or absorbed dose.

Scientific data accumulated over the past fifty years do not support the classification of food irradiation as a food additive. Foods treated by irradiation with cobalt-60 or cesium-137 (each emits pure gamma rays), electrons generated by a machine with maximum energy of 10 MeV, and
X-rays generated by a machine with a maximum energy of 5 MeV (later changed to 7.5 MeV) do not become radioactive. Multi-generation animal feeding studies conducted with different types of irradiated foods never found any adverse effects attributable to the consumption these foods. Analytical data on radiation chemistry of foods and its components found that either no new compounds are formed in irradiated foods, or, if compounds are formed, that they are the same ones found in natural foods or foods treated by other processes (e.g., cooking), or are compounds of no toxicological significance. In short, there are more data demonstrating the safety of different types of irradiated foods than there are of foods treated by all other processes combined.

The safety of different types of irradiated foods has been evaluated by national and international experts (including those from the FDA) on several occasions since 1958. In particular, since the early 1960s, the FAO, IAEA, and WHO monitored and evaluated the safety of irradiated foods. From these evaluations, it became clear that:

- No radioactivity is induced in any food treated by the three types of radiation sources mentioned above.
- Food irradiation is a physical process for treating food similar to heating and refrigeration of food.
- Toxicity of any irradiated food cannot be demonstrated by credible scientific data.
- Food irradiated under prevailing good manufacturing practices is safe for consumption.
- The effectiveness of irradiation as a sanitary and phytosanitary treatment for food and agricultural commodities has been clearly demonstrated.

Based on the foregoing, in 2003, the Codex Alimentarius Commission adopted an international standard for irradiated food that endorses the safety and effectiveness of irradiation as a food process. The International Plant Protection Commission likewise approved international guidelines on irradiation phytosanitary measures in the same year. The standards and guidelines issued by these two international bodies are recognized by the World Trade Organization in its dispute settlement process in food trade.

The science on food irradiation has progressed significantly from 1958 when the FDA started regulating this technology as a food additive. The time has come for the FDA to accept modern science by regulating food irradiation as a food process, not as a food additive. By doing so, it can remove the burden of having to evaluate each and every type of irradiated food each time a petition is submitted. It can then devote its limited resources to regulate foods based on modern science to ensure the safety of food supplies for the public.

Meanwhile, the FDA should approve the petition on irradiated ready-to-eat foods, pending since 1999. Such approval will allow irradiation to be used to ensure the microbiological safety of fresh produce and other foods to be consumed raw or without further heat treatment. By not approving irradiation for this purpose, the FDA in effect has denied the right of the public to safety for a wide variety of foods.

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See also: Loaharanu's full report on *Irradiated Foods* [1] for the American Council on Science and Health.