FIRST COMMERCIAL IRRADIATION OF FOODS IN THE UNITED STATES

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On February 11, 1977, Radiation Technology, Inc. consummated the first commercial shipment of irradiated finfish to take place in the United States. Although this initial shipment was limited to about 22kgm of product, which were shipped via air freight in insulated containers to Rotterdam from Rockaway, New Jersey, the procedures utilized were no different then for a 40,000 pound container load. A prerequisite for this shipment was to obtain an approval from the appropriate Dutch Health Authorities, acknowledging that the importation of radurized codfish fillets would be permitted. Since the Netherlands had approved the use of radurized codfish fillets for unrestricted consumer consumption in 1976, it remained to undertake the processing and shipment and to await the inspection and testing results by the Dutch Ministry of Health. Sixteen days following shipment of the refrigerated fresh codfish, the results were received, "excellent product, no off taste or off odor...". The shipment of radurized codfish fillets from the U.S. to the Netherlands permitted the retail sale of low dose irradiated and refrigerated fish fillets up to approximately three weeks after processing, thereby opening up new and lucrative marketing opportunities with attendant savings in energy due to the reduced shipment of fresh product and naturally the consumer was the big winner by having the opportunity to get continuous supplies of fresh product with less spoilage and virtual elimination of Salmonellae contamination. Although this was the start of commercialization, previous work involving large quantities of seafood for research purposes played an important role in developing the processing technology and handling techniques.

As early as late 1970 and continuing through 1972, Radiation Technology, Inc. was under contract to a Canadian firm to help develop Salmonellae free frogs legs and shrimp that would have extended shelf life under refrigeration. Although we had no direct knowledge as to how far commercialization of these commodities may have proceeded around the world, we do know that the Dutch have approved the radiation processing of both of these items for consumer consumption, and it may very well be that the tens of thousands of pounds processed for feeding studies and other evaluations probably played a role in the ultimate approval. Since Radiation Technology was only involved with the processing protocol, we were only privy to feedback from our customers regarding the wholesomeness and microbiological evaluation which we were told were highly favorable. Whether or not these radurized products are now entering the United States is the subject of speculation and not surprisingly, the FDA has told us that they believe irradiated shrimp and possibly frogs legs are entering the U.S. market and they infer this from the fact that certain test samples not only are free of Salmonellae, but "appear to stay fresh longer." In spite of these inferences, we in the industry in the United States are forced to sit back and wait for the U.S. Food and Drug Administration to be "absolutely certain of the safety of the process" - an absurd bit of rhetoric, but highly effective in stifling initiative and the introduction of new technology.

I would not want our distinguished meat scientists to think that they will only hear about seafood and to complete the background presentation, I will review our other efforts involving red meats and poultry.

In my view, two of the most striking examples of the commercial prospects for radappertized meat products can be shown by the following experiences. The first effort involved an order in December, 1977, from the Fred Hutchinson Memorial Hospital in Seattle, Washington, for pre-cooked radiation sterilized hospital diet portions. Although similar product had been previously supplied by the U.S. Army Group at Natick, Mass., the work by Radiation Technology proved that private industry had the complete capability for providing a wide range of pre-cooked, individually packaged diet portions that require neither freezing nor refrigeration for long term storage. Although the diets supplied to the hospital, which included:

- o beef steak
- o hamburger patties
- o pork chop
- o boiled ham
- o pork sausage
- o chicken breast
- o baked ham

were done so only to insure sterility in the diets fed to terminally ill cancer patients undergoing chemotherapy and radiationtherapy, which causes a reduction in the body's ability to fight infection. An even larger commercial market exists for similar diet portions to be used for:

- o emergency rations
- o recreational food - hiking, camping, etc.
- o military use
- o remote area feeding
- o sailing voyages
- o "meals ready to eat" for the elderly and infirm

An opportunity to assess the commercial potential for non-hospital usage of radappertized diets came in September, 1978, when Radiation Technology received an order from Dr. Frank Sims, formerly head of Pathology of Women's College Hospital in Toronto, who was in the process of retiring from his Canadian position and planning a seven month solo ocean voyage to Fiji, where he is presently Medical Director. With no refrigeration provisions on board, we had a splendid opportunity to assess the commercial potential of radappertized diets. In essence, Dr. Sims reported that his general well being throughout the long and difficult journey could be attributed to his ability to obtain a continuous supply of protein throughout the voyage. My challenge to those of you in attendance at this symposium is to recognize the potential benefit to mankind that can accrue through our ability to process and store animal protein for extended time periods with no continuing energy requirement during the storage period. The years of plenty are on the decline, bureau-

crats who are in positions to impede progress no longer have the excuse that alternate suppliers exist and no hardhip will come for their decision to procrastinate approvals, even on a limited scale. Industry and scientific pressure must be brought to bear to clear up the uncertainties and to move quickly while the overabundance of food supplies still exist.

Of some significance to this group was the use of nitrite free meat products that were supplied to Dr. Sims for his ocean voyage. Besides the diets used for the hospital program, we included:

- o Nitrite Free Bologna
- o Nitrite Free Hot Dogs
- o Nitrite Free Pork Roast

Presently, Radiation Technology, Inc. has submitted three petitions to the U.S. Food and Drug Administration calling for approvals for radiation preserved food products. As far as we know, these are the only current submissions still actively under review by the FDA. The petitions include:

TITLE	MAX. DOSE	DATE OF SUBMISSION
Radurization of Pre-Packaged Poultry	7 kGy	1978
Radappertization of Pre-Packaged Sterile Hospital Diets	50 kGy	1978
Radurization of Pre-Packaged Spice	10 kGy	1980

The last decade of experimentation involving radiation preservation of food has permitted us to establish protocols for the Good Manufacturers Practice (GMP) involving this area of work. The steps considered pertinent are outlined below:

1) Verification of proper minimum dose in order to establish an effective process. This step is accomplished by use of sub-lethal doses on product samples or innoculated product containing challenge organisms. Recovery of the microorganisms after irradiation permits plotting the log of the organism count versus dose on a semi-log plot. The slope of the resultant curve is the D10 value (dose required to obtain a factor of 10 reduction in the initial count).

   It is important to conduct the minimum dose verification work at the temperature at which full scale processing will take place since lower temperatures will usually result in higher D10 values, which could lead to less dose than required in the actual process. If the facility is to be used for processing against an accepted National or International protocol, this step can be omitted.

2) Dose distribution data must be obtained for the actual process conditions. This work can be performed on dummy product or preferably on a pilot shipment. We utilize a 27 point matrix and properly calibrated chemical dosimeters prepared in accordance with International standards (1). Since the dose distributions will be a factor of the source-to-target geometry and bulk density of the product, it is possible to utilize chemical dosimetry even for radappertized product doses at normal temperatures rather than sub-zero temperatures which would freeze the dosimeters.

3) Temperature distribution profiles are obtained on dummy product or preferably a pilot load. RTI utilizes multipoint thermocouple determinations in order to veryify the maximum temperature to be expected due to gamma heating of the product. It is important to conduct this experiment while the irradiation facility is in a period of high utilization so that the conveyor system and other support structures are at a maximum equilibrium temperature. This temperature contribution factor can very often overshadow gamma heating effects, especially for low-dose processes. It should be emphasized however, that microorganism kill due to gamma radiation is usually enhanced by increased temperatures, so that the process effectiveness may be enhanced by the temperature rise during the processing.

4) Set up proper record keeping and data entry procedures including:
   a) Copy of bill of lading and receiving ticket.
   b) Warehouse location and storage temperature.
   c) Office processing lot number on each carton to be processed together with a go-no go color change indicator.
   d) Batch record book data entry to conform to written work order including customer number, quantity of product processed, description of product, placement of biological indicators if required, minimum and maximum dose delivered, maximum temperature attained during processing.
   e) Warehousing location and temperature record after processing.
   f) Bill of lading for shipment out containing proper labeling as per International convention.
   g) Dosimetry certification.

   NOTE: A written protocol should be established for each product prior to initiation of routine processing.

By virtue of our experience in establishing product protocols and operating under FDA Good Manufacturing Procedures for our work in medical product and pharmaceutical sterilization, RTI has adopted a dosimetry system based on the highly accurate determination of the processing time for a given run based on the time required to conduct the particular prototcol at some previous date when the dose distribution data was obtained. Since Cobalt-60 decays at the rate of 1.025% per month, one must only assure that the processing time has been increased accordingly for a given Cobalt-60 source load. We have also developed techniques for irradiating product at sub-zero or refrigeration temperatures or to conduct certain irradiation in an oxygen free environment. In order to be able to process large quantities of varied products in an efficient manner while still maintaining close control over all processing variables, we have developed a new irradiator design concept based around a highly versatile conveyor system which we call the RTI Model #4101, or where provision is made for temperature (T) or environmental (E) add-ons, the Model 41-TE-1. Briefly, the 4101 can provide the following:

1) Automatic high dose rate processing.
2) Automatic low dose rate processing.
3) Controls for four (4) separate and distinct protocols to be processed automatically.
4) Product identification system to insure that so much product as called for was in fact processed.
5) Automatic print-out of processing parameters to verify processing times and minimum dose delivered.
6) Permits versatility in customer product packaging by permitting shipping cases up to 24" x 26" (61cm x 66cm) with loading heights of up to 72" (183cm). Each conveyor carrier can take loads up to 1,000 pounds (455kg).
7) Small loads can be handled as efficiently as large loads.
8) Computer controls lessen likelihood of operator error in processing.

A more detailed description of the prospects of Commercialization of Radiation Preservation of Food in the United States was presented by Drs. Welt and Sage (2) at the FAO/IAEA Advisory Group Meeting on Comparative Analysis of the Economics and Energy Requirements of Food Irradiation and Other Food Preservation Methods, held 17-21 September, 1979, in Vienna, Austria.

The first RTI Model #4101 irradiator facility is now under construction in West Memphis, Arkansas, with additional sites now being considered, both in the United States and overseas. The West Memphis facility is being operated by our wholly owned subsidiary, Process Technology, Inc, and is due to begin operation in November, 1980. Ultimate plans for the West Memphis site include a refrigerated storage warehouse, packaging facility, electron beam irradiation facility and a distributuon center. Although we regard a gamma irradiator to be the backbone of bulk food processing, we do believe that certain pre-packaged items such as tray packs, and luncheon meats may be processed with E.B. as an adjunct to gamma processing. The choice of West Memphis as our initial processing center after Rockaway, New Jersey, was prompted by many factors but the most important were proximity to a major distribution center, established customer base in the area, and proximity to excellent highways, rail, air and barge transportation. Above all was the excellent reception given our company by the Arkansas State Government, and the City Government of West Memphis. Similar factors will play a role in the location of subsequent facilities.

REFERENCES:

1. Manual of Food Irradiation Dosimetry, IAEA Technical Reports Series No. 178, Vienna, 1977

2. Welt,M.A. and Sage, G. "The Commercial Prospects for the Radiation Preservation of Food in the United States of America", FAO/IAEA Advisory Group Meeting on Comparative Analysis of the Economics and Energy Requirements of Food Irradiation & Other Food Preservation Methods, Vienna, Austria, September, 1979.