THE NATIONAL FOOD IRRADIATION PROGRAM CONDUCTED BY THE DEPARTMENT OF THE ARMY

ARI BRYNJOLFSSON

Radiation Preservation of Food Division
Food Engineering Laboratory
U.S. Army Natick Research and Development Command
Natick, Massachusetts 01760

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ABSTRACT

This article reviews the history of the food irradiation program in the USA and gives the status and future plans for research and development in food irradiation as of August 1976.

INTRODUCTION

During the last 200 years we in the United States have learned to cultivate our land so effectively that we reap a surplus of food — enough to feed 40 persons for each one working on production. We have learned to dig for minerals and use them to build everything that imagination and inventiveness can create. We have learned to harness the diversified energy resources to do the work for us. Before the beginning of this century, our technology had already surpassed Europe's technology, and by the end of World War II, our technology was a wonder to the rest of the world. Since then each country exposed to this technological wonder has sought to import and adopt it as fast as technical training and education of their people permitted. As a consequence, the world is changing at a faster rate than ever before.

This fascinating 200-year evolution, spearheaded by man's ingenuity in taming the forces of nature, led us into the nuclear age. This new age changed our outlook. We had been obsessed in conquering nature. We had gained knowledge, but, at the same time, greater destructive capability than ever before. Our chief challenges now were to retain the beauties of nature and to maintain peace throughout the world. We had harnessed the forces of nature. Now we had to preserve our environment and to harness the forces within man himself.

At the beginning man witnessed and feared the destructive power of

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his new knowledge about the forces in the nucleus of the atom. It was the destiny of this nation to be the first to understand nuclear power and to spearhead the course of mankind towards using this power for peaceful purposes.

One of the most important milestones on this route was President Eisenhower's "Atoms for Peace Program," which he proposed in his address to the General Assembly of the United Nations on December 8, 1953.

The dormant energy in the nucleus of the atom could be released to power our tools and heat our houses. Radioisotopes could be used not only in medicine to cure cancer, but also in many scientific investigations where the radioisotopes could show us the position and route of atomic elements so that we could trace them in physical, chemical, and biological processes. Atomic energy could be used to increase production of fertilizers. Radioisotopes used as tracer elements could aid in determining the most effective application of the fertilizers. Nuclear radiation could be used for sterilization of medical supplies. Radiation could be used for genetic transmutations in plant breeding aimed at increasing the quantity and the quality of food. Radiation could also be used to preserve the produced food by cutting down the large food wastage due to insects, parasites, and bacteria. Food could be made available to the hungry people all over the world regardless of the absence of costly refrigeration facilities and mechanized distribution systems. Not only would we reduce hunger, but we would also improve health by reducing or eliminating food-borne diseases. Consumers all over the world would benefit.

This "Atoms for Peace Program" has set an example of a course for mankind to follow in the next 200 years. To maintain peace and to tame the forces within man himself, we have to eliminate hunger and malnutrition for all.

Exploratory investigations during the first half of the century had shown how very effective radiation was in eliminating microbial growth, but the high costs of radiation sources precluded its use for preserving food. The technology evolution had now made preservation by irradiation economically feasible. The early ideas were sometimes molded by dreams of radiation as a panacea for preservation of food. This early optimism was an important driving force through most of the 1950's, and it resulted in tremendous efforts in developing this food preservation technology and in proving its safety. In the United States much of this work was spearheaded by U.S. Army food research laboratories and the Office of the Surgeon General of the Army. In the following discussion we will review the Army's efforts in this great

undertaking through our early short- and long-term studies, problems and achievements, cooperative work with other agencies, technological advances, current studies, and scheduled plans for the ultimate attainment of our goals.

Short-Term Toxicological Studies

By 1942 the U.S. Army was supporting some exploratory work in food irradiation at the Massachusetts Institute of Technology. In 1948, the Army Medical Nutrition Laboratory, Denver, Colorado, initiated toxicity studies of irradiated foods (Kraybill 1955). By 1955, the Army systematically had carried out short-term (usually 8 to 12 weeks) toxicity studies of 45 foods. In no case were any toxic effects found (Progress Report on Atomic Energy Research 1956). These short-term animal feeding studies were followed by short-term feeding studies using human test subjects. Subsequently, many more food items were tested in short-term animal feeding studies.

The 54 food items listed in Table 1 were tested in the years 1955 and 1959 in 7 short-term animal feeding studies using human volunteers (Progress Report on Atomic Energy Research 1956; Plough *et al.* 1960; Kraybill 1958). In these tests the caloric intake of irradiated foods was 32 to 100% for a period of 15 days. A thorough medical examination of the individuals was made, and clinical procedure was followed to check many of the measurable physiological and biochemical indicators of these individuals; in no case were there any indications whatever of toxic effects due to consumption of irradiated foods.

Long-Term Toxicological Studies

In 1956, following the completion of short-term studies on many of the food items, The Surgeon General initiated a systematic, long-term, animal feeding study program to check the toxicity and the nutritional quality of 22 representative irradiated foods (Read 1960; Reber *et al.* 1966). The protocols were made by consulting extensively with a great many specialists from the National Research Council and Food and Drug Administration. These protocols conformed to the best standards of that time. The 22 foods fed to rats, dogs, mice, and monkeys for 2 years to determine their possible chronic toxicological effects, carcinogenicity, and nutritional adequacy are listed in Table 2.

The many long-term animal feeding studies were of unparalleled scope and magnitude. Never before had any food processing method been tested so thoroughly.

Table 1. Fifty-four foods tested on humans in short-term toxicological studies

Meat Items	Fish Items	Vegetable Items	Fruit Items	Cereal Product Items	Miscellaneous Items
Bacon	Cod	Asparagus	Dried apricots	Bread	Dessert powder
Corned beef	Haddock	Green beans	Cherries	Crackers	Powdered whole milk
Ground beef	Salmon	Lima beans	Dried fruit compote	Cereal bar	Peanut butter
Beef steak	Shrimp	Beets	Melon balls	Flour	Pineapple jam
Chicken	Tuna	Brussel sprouts	Oranges	Macaroni	Strawberry jam
Chicken stew		Cabbage	Orange juice	Nut roll	Sugar
Frankfurters		Carrots	Peaches	Pound cake	
Ground ham		Cauliflower	Dried pears	Rice	
Ham steak		Celery	Strawberries		
Ground pork		Cole slaw			
Sausage		Corn			
		Mushrooms			
		Peas			
		Sweet potatoes			
		White potatoes			

Table 2. Twenty-two foods tested in the long-term toxicological studies during 1956–1959 period

Ground beef	Chicken	Corn
Pork loin	Chicken stew	Flour
Bacon	Cabbage	Fruit compote
Beef stew	Carrots	Pineapple jam
Tuna	Green beans	Peaches
Shrimp	White potatoes	Oranges
Codfish	Sweet potatoes	Evaporated milk
		Dried eggs

Contraction of the Army Program in 1959

Concurrently with the long-term animal feeding studies, the Army made plans to erect a food-irradiation pilot plant. Inevitably, problems unrelated to toxicity of irradiated foods were encountered in the animal feeding studies, and these problems often could not be explained without further testing. Therefore, on October 22, 1959, the Director of Research and Development, Department of the Army, suspended the erection of the planned food-irradiation pilot plant in Stockton, California (National Food Irradiation Research Program 1959). Most people assumed this decision indicated that irradiated foods were not safe. This misunderstanding sent a shock wave around the world, impeding or halting food irradiation research everywhere (Nucleonics 1959). Although Kraybill made it clear (Kraybill 1960) that there was no evidence of any toxicity in irradiated foods, the impact of the fiscal decisions already made could not be reversed.

The Completion of the Long-Term Toxicological Studies in 1965. The Food Irradiation Process is Found to be Safe

The Office of The Surgeon General of the Army, who had responsibility for the long-term toxicity testing, continued the animal feeding testing to clarify and resolve the problems. These tests, which continued through 1964, confirmed that the problems encountered were due to our deficient knowledge about nutrition in general and were unrelated to the irradiation processing of the food. In 1965, after completing the evaluation of the many long-term toxicological studies of the 22 representative food items, The Surgeon General's scientists concluded that:

> "food irradiated up to absorbed doses of 5.6 megarads with Co-60 source of gamma radiation or with electrons with energies up to 10

million electron volts have been found to be wholesome; i.e., safe, and nutritionally adequate," (Radiation Processing of Foods 1965).

Clearly the Office of the Surgeon General of the Army concluded that the 22 food items tested were representative of all foods, that the great many tests conducted proved the safety of foods preserved by ionizing radiation, and that the food irradiation process consequently, should get a broad or general clearance. That such broad clearance was a consequence of negative finding of toxicity in all the 22 tested foods was in accordance with views of the many scientists who had planned the entire approach to resolving the question of wholesomeness of irradiated foods, including the scientists of the Food and Drug Administration (FDA) (Commissioner of Food and Drugs 1960).

Participation by the Atomic Energy Commission and Clearances by the Food and Drug Administration of Individual Items 1960-1968

The Army had spearheaded the National Food Irradiation Research Program through the 1950's. In January, 1960, after the contraction of the Army Program in the fall of 1959, the Atomic Energy Commission (AEC) initiated a food irradiation research program with emphasis on low dose application. The Army program then became more concerned with high dose applications, especially radappertization (sterilization) of meats, poultry, and fish.

While the toxicological questions were considered resolved, the Army and the AEC continued to support research and development aimed at improving the irradiation engineering and the quality of irradiated foods with regard to taste, color, stability, microbiological safety, and packaging. The Army also petitioned the FDA for clearance of bacon, which packed under vacuum was fairly stable in storage and acceptable. The clearance was granted on February 8, 1963. FDA further granted clearance for irradiated wheat and wheat products on August 21, 1963, irradiated for insect disinfestation; for irradiated white potatoes on June 30, 1964, irradiated for sprout inhibition; and for irradiated packaging materials in the years 1964 to 1967 to be used in contact with foods.

The Petition to FDA for Clearance of Ham

The Army petitioned FDA on August 15, 1966 for clearance of ham packaged under vacuum and radappertized at room temperature. This ham was stable under storage at room temperature and highly accep-

table. In January, 1966, FDA raised questions about the validity of clearing ham based on the data obtained in the studies with bacon and pork, and FDA was also concerned about the loss of thiamine in irradiated pork. In March, 1967, the National Academy of Sciences-National Research Council Committee on Radiation Preservation of Food and The Army Surgeon General's Advisory Committee on Nutrition reviewed the questions posed by FDA. The Committees endorsed as valid the interpolation of pork and bacon data to ham. The Committees maintained that man could get sufficient thiamine from other dietary sources to meet the daily requirements. In April, 1968, the FDA nevertheless turned the petition down on the grounds that the data submitted were insufficient to prove safety. This denial of approval of irradiated ham resulted in great reduction of research and development of irradiated foods throughout the world. Many proponents of food irradiation became frustrated and stopped promoting the R and D efforts. In discussion with FDA officials, it became clear that new wholesomeness studies were mandatory to satisfy current FDA requirements (Status of the Food Irradiation Program 1968).

Renewed Long-Term Toxicological Studies on Beef

A new protocol for animal feeding studies on ham was then designed by the scientists at Natick Research and Development Command and at the Office of The Surgeon General in close cooperation with FDA's scientists. Meanwhile, the food technology research and development at Natick had resulted in good quality radappertized beef which was highly stable in storage when blanched at 343°K (70°C), vacuum packed, and irradiated at 243°K (-30°C). Beef, which is the most important meat item in the American diet, was then selected (rather than ham) to be the first meat for testing in the renewed wholesomeness studies. Beef also had the advantage over ham that it did not contain any nitrites or nitrates, which by then had become suspect. The new animal feeding studies were very extensive. It was considered reasonable to be cautious and to start with only one meat item. The contract for the animal feeding studies of beef was awarded in March, 1971, to a private contractor, who started the tests with the first generation of animals in the fall of 1971.

The animal feeding studies were designed to compare any measureable biological indicator of experimental animals fed irradiated beef against the same indicators of control animals fed nonirradiated beef. The animals fed irradiated beef were divided into 2 groups, 1 group fed gamma ray irradiated beef and another group fed electron irradiated

beef. The control animals were likewise divided into 2 groups, 1 fed heat-sterilized beef, the other group fed beef stored frozen. The two groups fed irradiated beef can be considered equivalent because the gamma rays generate the fast electrons, which in turn are responsible for practically all the ionizations and excitations. In both cases, therefore, we are dealing with electron irradiated beef. In one case the electrons are generated by gamma rays, and in the other case the electrons are generated by accelerators. Also, the two control groups can be considered equivalent, because both are assumed to be inert from a toxicological point of view. Some scientists do prefer, however, to consider the frozen beef as the proper control, because heat destroys some of the nutrients, while others would actually prefer the heat-sterilized beef as the control, because heat may inactivate some toxic compounds possibly present in the beef, and also because radappertization is intended to replace heat-sterilized beef rather than frozen, stored beef. To satisfy each and every scientist, the studies were designed with the four separate groups. These animal feeding studies were completed on December 31, 1976. Details of these studies have been previously described (Raica and Baker 1972, Johnson *et al.* 1974; Baker 1976).

Technological Improvements

Concurrent with the animal feeding studies, the food technology research and development at Natick improved the texture, color acceptance, and storage stability of many other food items. These improvements have been obtained by inactivating proteolytic and autolytic enzymes in the meats at 343 to 348°K (70 to 75°C) prior to irradiation. This preirradiation treatment resulted in less off-flavors and provided increased storage stability. The packaging under vacuum resulted in reduction of oxidation, rancidity, and peroxides. Irradiation of the meat in the frozen state reduced the radiation chemical processes occurring in the water in the meat (approximately 2/3 by weight). This factor is especially important for some of the water soluble micronutrients like vitamin B_1 which acts as a scavenger for the radicals produced in the water and is thereby destroyed. When the meat is irradiated at room temperature, the B_1 vitamin is destroyed to the same extent as in the heat sterilization process. On the other hand, when irradiated in the frozen state, the vitamin destruction is small. Since the withdrawal of the ham petition in 1968, the research in the radiation chemistry of the proteins, the lipids, the carbohydrates, and the vitamins has continued and has been well elucidated by use of pulse radiolysis techniques, modern electrophoretic techniques, fractionation of

volatiles, gas chromatography, and liquid chromatography followed by mass spectrometric analysis. The conventional electron spin resonance (ESR) techniques have been used to study the fate of radicals. These studies will soon be supplemented by fast ESR techniques. The principal value of these chemical studies is for extrapolating and interpolating data obtained in the animal feeding studies and for investigating irradiation effects as a function of temperature and dose.

The radappertizing (sterilizing) irradiation dose for meats irradiated at 243° K (-30° C) is found to be around 40 kJ/kg (= 4 million rad) for non-cured meats and around 30 kJ/kg (= 3 million rad) for cured meats. A radappertizing dose is the irradiation dose that will reduce the initial number N of *C. botulinum* spores to a number $N \cdot 10^{-12}$.

The radiation source technology and the irradiation technology have also improved considerably since the 1960's, due to the greatly increased irradiation processing in other branches of industry: in the medical industry for sterilizing of medical products; in the cable industry for producing shrinkable films and for polymerizing the plastic in monomer impregnated wood for greater hardness and durability; in the auto industry for curing coatings and paints; and in the garment industry for grafting monomers to fibers for crosslinking and for polymerizing monomers.

Renewed Long-Term Toxicological Studies on Chicken, Pork, and Ham

In 1975, after a thorough review of the progress made, the Assistant Secretary of the Army for Research and Development directed an accelerated program to assess wholesomeness concurrently for three additional radappertized meat items: chicken, pork, and ham. The research protocols for the animal feeding study portion of the wholesomeness studies of these three items have been made by the scientists within the Army in consultation with a great many experts in the United States and abroad, including those with the National Research Council Committees and with the Food and Drug Administration. The contracts for these studies were awarded June 1, 1976 and were monitored by The Army Surgeon General's Office. The meats for the first year consumption by the animals have been processed by industry and irradiated at Natick. As in the case of the beef studies, research on food technology, microbiology, radiation chemistry, induced activity, and irradiation processing as well as the overall direction of the food irradiation program are the responsibilities of U.S. Army Natick Research and Development Command.

The flow diagram showing the major operations and milestones as a function of time are shown in Fig. 1A to 1D.

While such flow diagrams give a good overview and serve well as a management tool, perturbation of plans involving animal studies of this magnitude are rather common. Having learned from the difficulties encountered in the beef studies, we are hopeful, however, that we will be able to progress on schedule.

Future Petitions to FDA

The petition to FDA for approval of irradiated beef was submitted in the fall of 1977. We hope to submit petitions to FDA for clearance of chicken, pork and ham in 1981. The petitions will be in six volumes; each volume will be written by specialists in the subjects and reviewed by a great many experts. The table of contents for the beef petition is shown in Table 3, "Animal Feeding Studies." Volume V in the Table will be the main part and contain most of the supporting data for the petition to FDA.

Based on our present data, we believe it likely that we will succeed in proving to FDA that enzyme-inactivated radappertized beef, chicken, pork, and ham are wholesome. We are hopeful that we will also succeed in expanding FDA approvals of the above items to cover a broad spectrum of foods. The petitions for expansions of the approvals will be supported by numerous other feeding studies sponsored by the U.S. Army in the 1950's and the 1960's, by AEC in the 1960's, as well as studies done in many other countries (for instance, Japan, England, the Netherlands, Canada, and India) and by the International Project in the Field of Food Irradiation in Karlsruhe, Germany. We are also hopeful that gradually the world will come to recognize that the food irradiation program, when properly used, will significantly help reduce suffering from hunger, malnutrition, and food-borne diseases, and that the process in no way impairs nutrition of the food nor compromises safety in its consumption. As a consequence, throughout the world there will be fewer people hungry and fewer people suffering from food-borne diseases over the next 200 years.

Table 3. Table of contents for the beef petition

Vol. I. Irradiation Technology
- A. Nature of Radiation to be Used
- B. Irradiation Facilities
- C. Irradiation Dosimetry
- D. Induced Radioactivity
- E. Irradiation Control

Vol. II. Processing and Packaging Technology
- A. Processing and Handling of Beef
- B. Other Beef Formulations
- C. Packaging
- D. Proposed Regulations

Vol. III. Microbiology
- A. Microflora in Beef
- B. Radiation Effect on Vegetative Bacteria
- C. Radiation Effect on Spore Forming Bacteria
- D. Radiation Effect on *C. botulinum*
- E. Radiation Effect on Virus and Rickettsia
- F. Effect on Enzyme Inactivation
- G. Effect of Irradiation Temperature
- H. Sanitary Microbiological Standards

Vol. IV. Radiation Chemistry of Food
- A. Basic Concepts
- B. Proteins
- C. Fats and Lipids
- D. Carbohydrates
- E. Vitamins
- F. Minerals
- G. Free Radicals; "Stored Energy"
- H. Review of Radiation Chemistry

Vol. V. Animal Feeding Studies
- A. Toxicity and Carcinogenicity of the Total Diet
- B. Mutagenicity
- C. Teratogenicity
- D. Antinutritional
- E. Protein Efficiency
- F. Toxicity and Carcinogenicity of the Radiolytic Products
- G. Review of all Related Animal Feeding Studies

Vol. VI. Proposed Regulations and Controls for Irradiation of Beef and Distribution of Beef
- A. Licensing Control and Operation Control of Food Irradiation Facility
- B. Food Processing Controls and Labeling Requirements
- C. Sanitary and Microbiological Standards and Handling of the Food During Processing

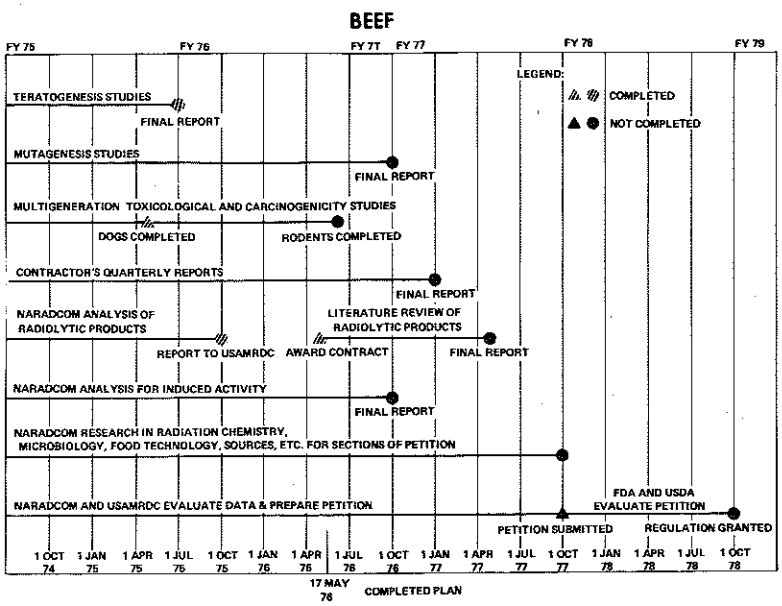

FIG. 1A. FLOW-DIAGRAM FOR THE WHOLESOMENESS STUDIES ON RADAPPERTIZED (47 TO 71 kJ/kg) BEEF AND FOR PETITIONING FDA FOR APPROVAL

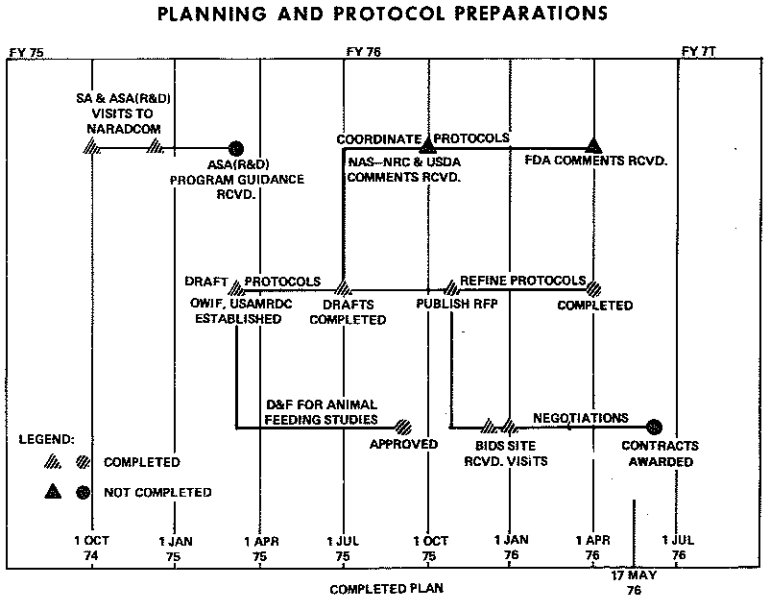

FIG. 1B FLOW-DIAGRAM FOR PREPARATION OF THE PROTOCOLS FOR THE ANIMAL FEEDING STUDIES OF RADAPPERTIZED HAM, PORK, AND CHICKEN AND CONTRACTING THE RESEARCH TO A PRIVATE CONTRACTOR

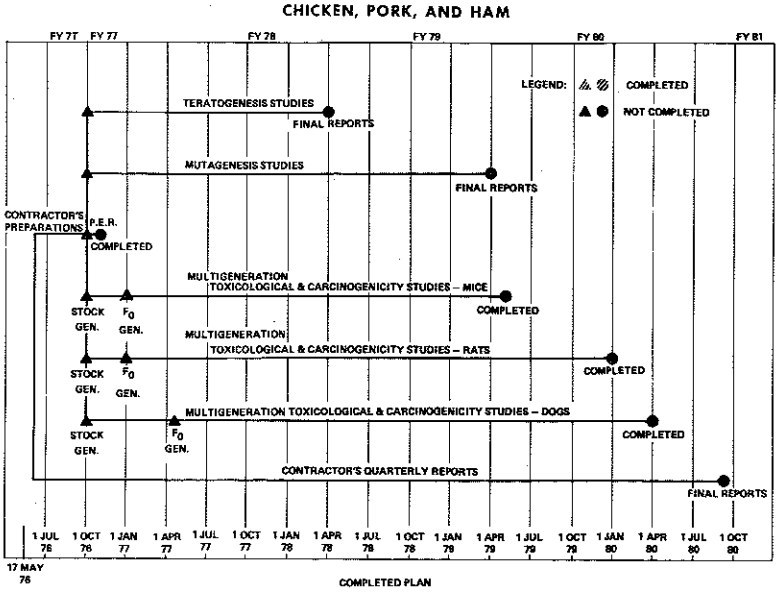

FIG. 1C FLOW-DIAGRAM FOR THE ANIMAL FEEDING STUDIES ON HAM, PORK, AND CHICKEN DONE BY CONTRACTORS

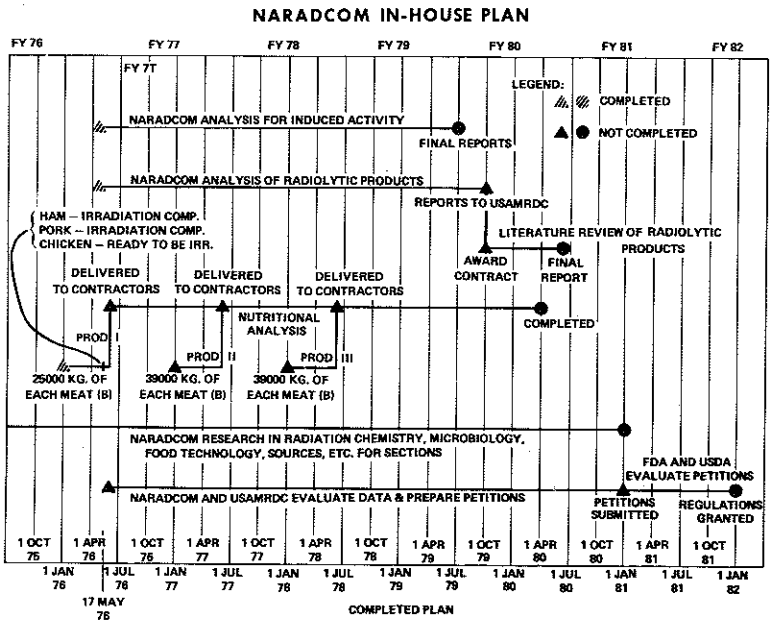

FIG. 1D FLOW-DIAGRAM FOR THE RESEARCH AT NATICK RESEARCH AND DEVELOPMENT COMMAND (NARADCOM) RELEVANT TO THE WHOLESOMENESS STUDIES OF RADAPPERTIZED HAM, PORK AND CHICKEN

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