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The Department of the Army's Food Irradiation Program: Is It Worth Continuing? PSAD-78-146; B-146700. September 29, 1978. 42 pp. + 4 appendices (7 pp.).

Report to Rep. Thomas J. Downey; by Robert F. Keller, Acting Comptroller General.

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Authority: Food Additives Amendment of 1958 (P.L. 85-929; 72 Stat. 1784). Federal Food, Drug and Cosmetic Act.

Food irradiation technology, being developed by the Department of the Army, uses high doses of radiation to sterilize meat and poultry products. In the last 25 years, the Department of Defense has spent about $51 million on research on this technology. Food irradiation is classified with food additives and requires Food and Drug Administration (FDA) approval before its public use. Findings/Conclusions: The Army's food irradiation program, while not yet succeeding in obtaining FDA approval of irradiated meats, has made progress in advancing the state of the art. A large portion of work performed in a renewed effort to obtain data to meet FDA requirements was wasted because the Army did not adequately review the contractor's work which was later found to be unacceptable. Although default by the contractor hampered progress toward obtaining FDA approval, the Army believes that, with continued satisfactory studies, it could obtain approval of irradiated chicken by September 1983 at an additional cost of about $10 million. Cost estimates for restarting other animal feeding studies to obtain FDA approval and for completing the study on irradiated chicken range from $28 million to $47 million. Some food irradiation proponents believe that classifying food irradiation as a process rather than as an additive would facilitate its commercial adoption, but GAO found no basis for this belief. A potential benefit of irradiated meats for use in military rations is that no refrigeration would be required during storage. However, irradiation of foods may be economically unfeasible because of its lack of acceptance in the

commercial market. Recommendations: The Secretary of Defense should have the Secretary of the Army develop a plan to complete the food irradiation program. The plan should: restrict animal feeding studies to those needed to obtain approval of irradiated chicken; evaluate the need for continuing food irradiation research at the $3-million-a-year level; and determine, using irradiated chicken as a test case, the desirability of further Government investment in high-dose sterilization of meats and the potential for successfully transferring the technology to industry. (HTW)

7914

REPORT BY THE

Comptroller General

OF THE UNITED STATES

The Department Of The Army's Food Irradiation Program-- Is It Worth Continuing?

In the last 25 years, the Department of Defense has spent $51 million on food irradiation research. The Army's food irradiation program is directed at using high doses of radiation to sterilize meats, thus preserving them from spoilage. The objective is to use irradiated meats in military rations.

Despite the years of research, the Army has not yet convinced the Food and Drug Administration that irradiated meats are safe and nutritious. Legal, scientific, and economic barriers must be dealt with before radiation sterilized meats can be used in military rations.

PSAD-78-146
SEPTEMBER 29, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-146700

The Honorable Thomas J. Downey
House of Representatives

Dear Mr. Downey:

This report responds to your August 5, 1977, request for a review of the Department of the Army's food irradiation program. It provides perspective on the problems encountered in the research program, the potential benefits from using radiation sterilized meats, and the barriers which must be dealt with in the technology adoption process.

As requested by your office, we did not take the additional time to obtain written agency comments. The matters covered in the report were discussed with officials of the principal agencies involved, and their comments were considered in preparing the report.

We are sending copies of this report to responsible congressional committees, Government agencies mentioned in the report, Representative Margaret M. Heckler, and others interested in food irradiation technology.

Sincerely yours,

ACTING
Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE HONORABLE THOMAS J. DOWNEY HOUSE OF REPRESENTATIVES

THE DEPARTMENT OF THE ARMY'S FOOD IRRADIATION PROGRAM--IS IT WORTH CONTINUING?

D I G E S T

The Army's food irradiation program, while not yet succeeding in obtaining Food and Drug Administration (FDA) approval of irradiated meats as safe and nutritious, has made progress in advancing the state of the art. FDA's rescinding approval of irradiated bacon and advances in other food technologies caused the Army to seriously consider scrapping the program in 1970; however, congressional interest caused the Army to continue.

After 25 years of research, costing about $51 million, the Army has not introduced irradiated foods into the military rations.

Extensive long-term animal feeding studies were begun in the early 1970s as part of a renewed attempt to obtain the data needed to satisfy FDA requirements. A large part of this new effort--$4 million spent on feeding studies on irradiated beef, pork, and ham--was wasted. The Army did not adequately review the work as it was done by the contractor, and the Army subsequently found the work to be unacceptable. The Army recently has intensified its monitoring of the remaining animal feeding study contract on irradiated chicken to ensure that the tests are properly conducted. (See pp. 13 to 20.)

The Army declared the contractor in default on the animal feeding studies on irradiated beef, pork, and ham, and this has had an adverse effect on the Army's time frames for obtaining FDA approval of irradiated meats. The Army believes that, if the irradiated chicken feeding study continues to progress satisfactorily, it might be able to obtain FDA approval for that meat item by September 1983 at an additional cost of about $10 million.

Cost estimates for restarting the beef, pork, and ham animal feeding studies to obtain FDA approvals and for completing the study on irradiated chicken range from $28 million (officials of the Natick Research and Development Command)

to $47 million (Army headquarters). (See p. 21.) GAO discussed food irradiation research matters with officials of the Department of Defense; Department of the Army; Food and Drug Administration; Department of Agriculture; Federation of American Societies for Experimental Biology; Committee on Food Irradiation of the National Research Council; and Industrial Bio-Test Laboratories, a subsidiary of Nalco Chemical Company.

GAO also solicited the views of six private food processors; three commercial radiation service firms; and others on the commercial prospects for, and their interests in, food irradiation.

LEGAL AND SCIENTIFIC BARRIERS

Food irradiation is included in the definition of food additive in the law and requires FDA approval before its public use. Satisfying FDA requirements involves extensive animal feeding studies and other laboratory research to demonstrate that irradiated foods are safe and nutritious.

Some food irradiation proponents believe that classifying food irradiation as a process in the law would reduce the extent of testing required and, consequently, facilitate commercial adoption of this technology. GAO found no basis to presume that changing the definition of food irradiation in the law would speed up adoption of the technology since FDA requirements would be the same whether food irradiation is termed a process or an additive. (See pp. 10 to 12.)

Some Defense and Army officials are skeptical that FDA will ever approve irradiated meats. Failure to obtain FDA approvals for meat in the past and FDA's increasingly close scrutiny of food additive petitions give some basis for this skepticism.

In spite of the problems with animal feeding studies, the Army's research, conducted and sponsored by the Natick Research and Development Command and presently funded at $3 million a year, has shown progress in acquiring

knowledge of and otherwise developing the food irradiation technology. Natick officials believe that the Army has sufficient research data, except for animal feeding studies, to support petitions to FDA for approving irradiated meats. (See pp. 22 to 25.)

ECONOMIC BARRIERS

Irradiated meats offer some potential advantages for use in military rations, especially since no refrigeration will be needed during long periods of storage. It has been long recognized that a substantial commercial market, in addition to the military market, would be needed to attract private investment in this technology. Recent improvements in thermal processing technology and the Army's practice of providing soldiers with fresh or frozen meats whenever possible because of their high acceptability could limit the impact irradiated meats would have on military rations.

The U.S. food industry has not commercially adopted those irradiated foods that have been approved by FDA (low-dose irradiation of wheat, wheat products, and potatoes). Therefore, FDA approvals do not ensure that a commercial market for the irradiated foods will exist. These factors emphasize the uncertainties about whether this technology would be practicable from an economic standpoint. (See pp. 26 to 35.)

RECOMMENDATIONS

The Secretary of Defense should have the Secretary of the Army develop a plan to complete the food irradiation program. The plan should

--restrict animal feeding studies to those needed to obtain approval of irradiated chicken;

--evaluate the need for continuing food irradiation research by Natick at the $3-million-a-year level; and

--determine, using irradiated chicken as a test case, the desirability of further

Government investment in high-dose sterilization of meats and the potential for successfully transferring the technology to industry.

AGENCY COMMENTS

GAO discussed its proposed report with Defense, Army, and FDA officials. Their comments and suggestions were considered in preparing the final report.

Army officials said they agreed with GAO's recommendations and were planning to implement them. With respect to continuing the food irradiation program after a successful petition to FDA and a decision for continued Government interest, Army officials said the present Army position is that some other Government agency should be responsible for establishing an irradiated food industry. They recognize that the Army would have a supporting role in the technology transfer process.

Contents

ABBREVIATIONS

AEC	Atomic Energy Commission
FDA	Food and Drug Administration
GAO	General Accounting Office
IBT	Industrial Bio-Test Laboratories, Inc.

CHAPTER 1

INTRODUCTION

In the last 25 years, the Department of Defense has spent about $51 million researching a food preservation technique called food irradiation. The Secretary of the Army is responsible for Defense's food research and development program, which includes the food irradiation program. Food irradiation technology, being developed by the Department of the Army's Natick Research and Development Command, uses high doses of radiation to sterilize beef, pork, and poultry products. Advantages cited by Army researchers for irradiated meats over meats preserved by other methods include improved quality, reduction or elmination of chemical food preservatives which may be cancer causing, and reduced dependence on refrigeration.

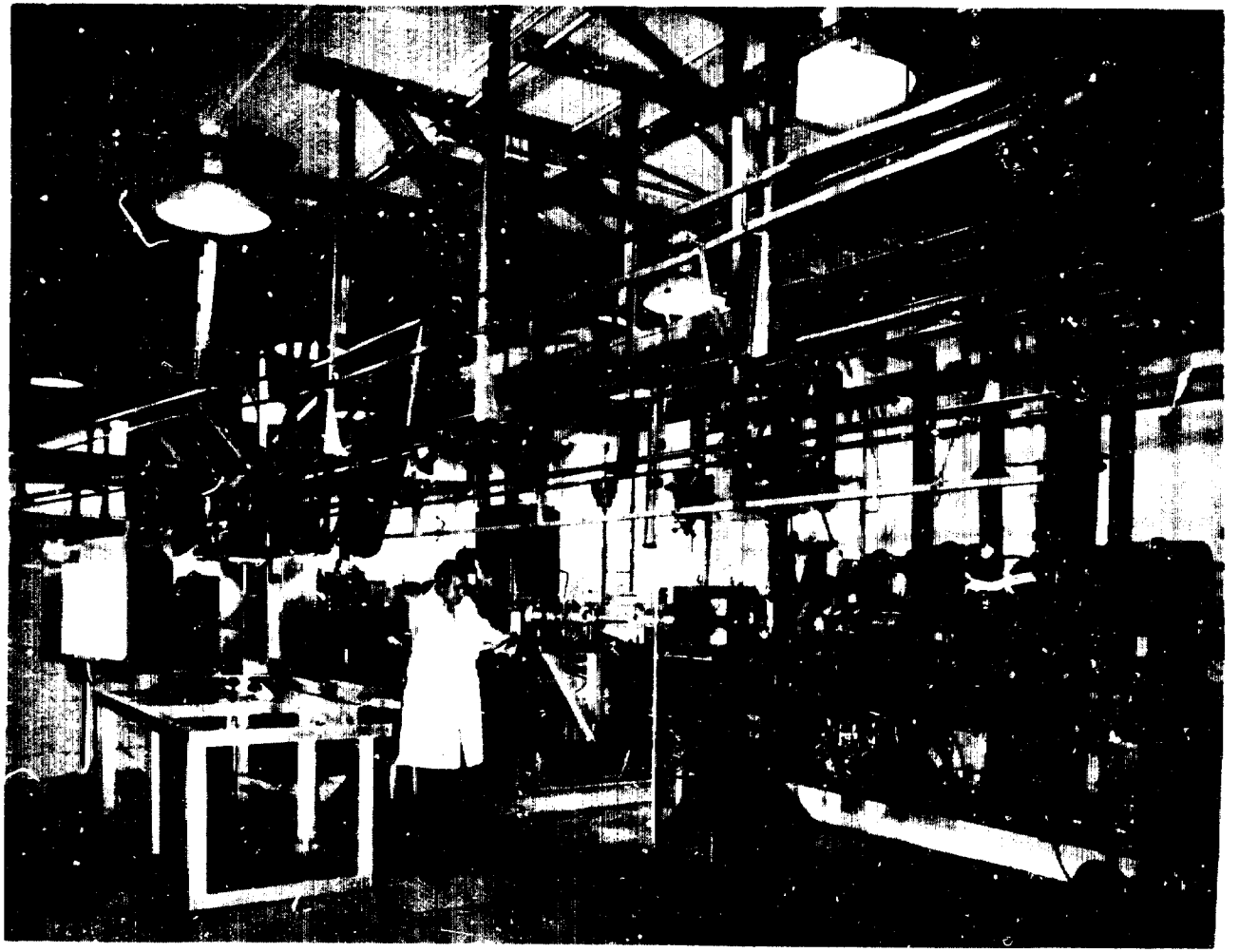
The Food Additives Amendment of 1958 (Public Law 85-929, 72 Stat. 1784) to the Federal Food, Drug and Cosmetic Act includes food irradiation in the definition of a food additive and requires Food and Drug Administration (FDA) approval of irradiated foods before its public use. The Army has made a number of studies for establishing the wholesomeness of irradiated foods; however, it has not yet convinced FDA that irradiated meats are wholesome; that is, safe and nutritious.

Noting the lack of success in obtaining FDA's approval and the amount of Federal funds invested in food irradiation research, Representative Thomas J. Downey asked us in August 1977 to examine the cost effectiveness of the Army's food irradiation program. (See app. I.) In January 1978 Representative Margaret M. Heckler expressed strong interest in the potential of preserving food by the irradiation process and specifically asked that our review address the question of whether food irradiation should be considered a food process, like thermal processing, rather than a food additive. (See app. II.)

IRRADIATION PRESERVATION OF FOODS

Since the 1940s researchers have been studying the use of ionizing radiation as a method of preserving foods. Food irradiation changes the molecular structure of foods by exposing foods to radiation sources, such as cobalt 60 or cesium 137, X-rays, or electrons from an electron accelerator. Electrons from atoms or molecules in the foods are displaced, creating free particles called ions. The ionized, activated molecules form unstable secondary products that kill microorganisms which cause meat, fish, and poultry to spoil. Irradiation of fruits and vegetables can also slow postharvest growth and maturation. (Fig. 1 shows an electron accelerator

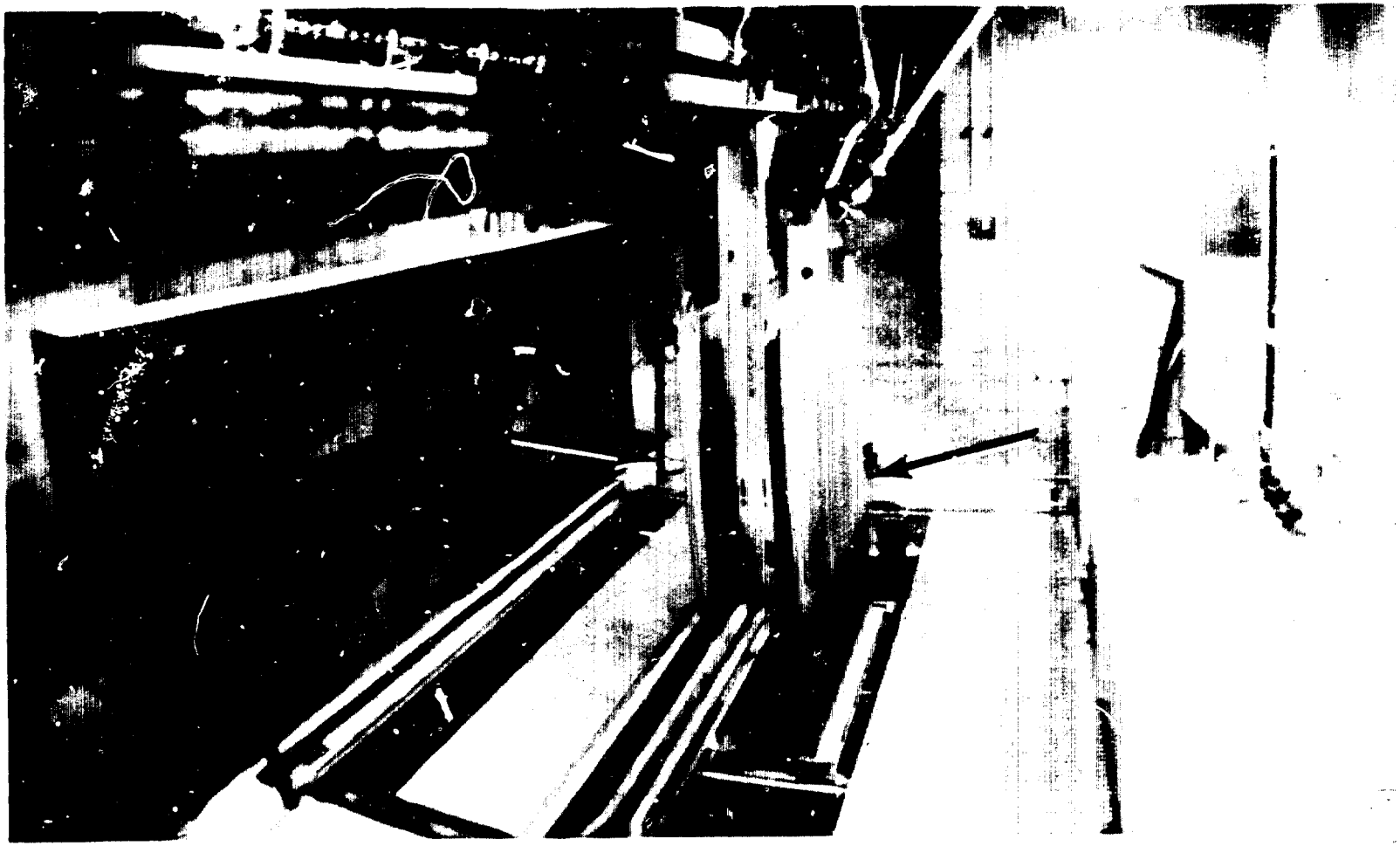
FIGURE 1



The electron linear accelerator at U.S. Army Natick Research and Development Command used for research in radiation chemistry of food and for irradiating food for the animal feeding studies. The accelerator is seen in the right of the picture. The food is irradiated in the white box on the left. (See arrow)

Source: Natick Research and Development Command

FIGURE 2



The Cobalt-60 facility at U.S. Army Natick Research and Development Command is used for research and development of the technology of irradiated foods and for irradiating the food for animal feeding studies. The Cobalt-60 sources form two rectangular planes in the center of the picture. The carrier holding several carton boxes with the cans of meat is between the two source planes. (See arrows)

Source: Natick Research and Development Command

and fig. 2 shows a cobalt 60 radiation source facility at the Natick Research and Development Command.)

Food irradiation generally involves either relatively high or low doses of absorbed radiation. Low-dose food irradiation exposes a food product to less than 1 million units of absorbed radiation soon after harvest or slaughter. High-dose food irradiation exposes precooked meat or poultry to 1 million or more units of absorbed radiation.

Low-dose irradiation (1) reduces micro-organisms enough to extend refrigerated shelf life of some foods, (2) inactivates bacteria posing potential public health hazards, (3) destroys insects infesting stored grains and fruits, (4) delays postharvest ripening of fruits, and (5) retards sprouting of potatoes and onions. FDA has approved low-dose irradiation of wheat and wheat products for insect disinfestation and sprout inhibition in white potatoes. In addition, high doses of radiation are used to sterilize beef, pork, and poultry products and thus eliminate the need for any refrigeration during storage. No foods preserved through high-dose irradiation are approved by FDA.

Proponents of food irradiation point out that this technology could help alleviate food shortages in areas of the world lacking modern transportation and refrigerated storage facilities. Commenting on the potential of the technology, one researcher recently stated that:

> "* * * Food irradiation will not solve all our problems. Food irradiation will not replace the now widely used techniques of food processing. But it will add to the choices we have. Food irradiation will take its place when and where it can produce nutritionally superior products, when and where it can ease storage and distribution problems, when and where it can improve the public health by reducing the hazards of foodborne disease and when and where it is preferred by consumers because of lower cost and improved quality."

ARMY PROGRAM

The food irradiation research program includes

--animal feeding studies which are the responsibility of the Army Medical Research and Development Command of the office of the Surgeon General and

--food irradiation research conducted and sponsored by Natick.

Data from animal feeding studies form a necessary part of any petition to FDA for approving irradiated foods. These animal feeding studies have cost about $11 million. Food irradiation research by Natick is also essential in providing data for any petition to FDA for approving irradiated foods. Research areas include radiation chemistry, microbiology, packing technology, processing technology, and irradiation technology. Natick's research is a continuing program funded at about $3 million a year.

Historical perspective

A 1953 Army feasibility study concluded that successful food irradiation would improve acceptablility of field rations, reduce logistical dependence on refrigeration, and greatly reduce military subsistence costs.

The Army has a requirement for any food process that provides a wholesome, good-tasting, economical, self-stable product. The food irradiation program has been justified on the basis that high-dose food irradiation can (1) provide sterilized food that has far better taste and texture than food preserved through canning, (2) reduce food handling costs, and (3) decrease the need for refrigeration.

From 1953 to 1960 the Army was responsible for both low- and high-dose food irradiation research. In 1959 the Army decided to do only high-dose research which, it believed, had the greatest potential to meet the military ration needs. In 1960 the Atomic Energy Commission (AEC), 1/ which had an early interest in food irradiation, assumed responsibility for low-dose research. AEC believed low-dose food irradiation had good potential for civilian uses, such as destroying salmonella in poultry and preserving fruits and vegetables.

The Army's interest in and commitment to food irradiation has varied considerably over the 25 years. On two occasions the Army and AEC had plans to construct pilot irradiation plants to introduce and test irradiated foods in military rations. In 1957 the Army planned to build a pilot irradiation plant in Stockton, California, to develop production techniques for irradiating foods and to produce sufficient quantities of irradiated foods to test their acceptability.

1/Now the Department of Energy.

Plans to build this facility were canceled after the Food Additives Amendment of 1958 was passed. This act required FDA's approval of irradiated foods.

At the Army's request, AEC, in 1967, contracted with a firm established by four other firms to construct a pilot meat irradiation plant. This plant would be used for irradiating meats, such as ham and poultry products for the military, and investigating, testing, and developing a commercial market for these meats. Defense agreed to purchase, from the firm, 300,000 pounds of irradiated meat each year for 3 years. Building this facility was contingent upon FDA approval of irradiated meats.

The Army had obtained FDA approval of irradiated bacon in 1963 and had petitioned FDA for approval of irradiated ham in 1966. FDA, however, rescinded the bacon approval in 1968, citing possible health problems with the test animals and deficiencies in the way some experiments were designed and conducted. The Army, although convinced that irradiated bacon and ham were safe, withdrew the petition for approval of irradiated ham. Because of the lack of FDA approval, plans for the pilot irradiation plant were dropped.

In January 1970 the Army attempted to discontinue its food irradiation program, citing the following reasons:

--Multiple technological approaches involving approved preservation methods have evolved since the start of the program and could be used to meet military ration requirements.

--The absence of any positive indications that further efforts to prove wholesomeness would be successful and form the basis for developing a civilian commercial base.

--It lacked a firm basis for estimating the total cost of proving irradiation's safety.

Because of congressional interest, the Army decided to continue its food irradiation program.

In February 1975 the Army initiated a study of the program to ensure that it was soundly planned and progressing at the most expeditious but realistic pace. That study concluded that, because an ongoing animal feeding study on irradiated beef indicated no radiation-related pathological problems, it would be appropriate to initiate concurrent studies on chicken, pork, and ham. The Army expanded the program in

March 1975 to include those three meats. The animal feeding studies were contracted to private laboratories. The Army estimated that it would submit petitions to FDA for approval of irradiated beef in 1977 and irradiated ham, pork, and chicken in 1981.

Default by animal feeding contractor and other problems hamper the program

In October 1977 the Army declared the contractor for animal feeding studies on beef, ham, and pork in default for deficiencies in conducting these studies. Data from these studies has been determined as being useless. The study on irradiated chicken is proceeding, although some problems experienced in that study have required the Army to revise its estimated date for petitioning FDA for approval of irradiated chicken from 1981 to 1982. Army cost estimates for completing the chicken study and redoing the beef, pork, and ham studies range from $28 million to $47 million. (See app. III for a chronology of the Army's food irradiation program.)

ROLES OF OTHER FEDERAL AGENCIES IN FOOD IRRADIATION

Other agencies which have sponsored food radiation research are the Departments of Energy, Commerce and Agriculture.

AEC, now the Department of Energy, engaged in applied food irradiation research activities from 1960 to about 1970, including:

--Developing irradiation source technology.

--Constructing and assuring the safety of irradiation facilities at Natick, the National Marine Fisheries Service, and other locations.

--Contracting for research studies on grain, papaya, fish, and other foods irradiated at low doses to establish their safety.

After 1970 AEC began phasing out food irradiation because of limited research funds and the low priority assigned to food irradiation research. The Department of Energy, however, contributes $27,000 annually to the International Project in Food Irradiation, Karlsruhe, Germany. (See p. 8.)

From 1965 to about 1976, the Department of Commerce's National Marine Fisheries Service did commercial feasibility

studies using low-dose irradiation to extend fish shelf life. This facility also irradiated fish and wheat for use in animal feeding studies for the International Project in Food Irradiation. The facility's irradiation efforts ceased about 1976 after demonstrating the commercial application of low-dose irradiation to extend refrigerated shelf life of fish and after completing irradiation work for the International Project.

In 1961 the Department of Agriculture initiated low-dose irradiation studies for controlling salmonella, preventing spoilage in poultry, and preventing spoilage and insect damage to fruits and vegetables. According to Agriculture officials, these studies stopped about 1966 because of a general loss of interest in food irradiation research and the doubt that consumers would accept irradiated foods because of their off-flavor. Although Agriculture has discontinued its in-house food irradiation research, some funds it distributes to non-Federal research activities are used for such research.

In the event that FDA approves irradiated meats and production starts, Agriculture would be responsible for assuring that irradiated foods are properly labeled, that the facilities are sanitary, that the meats to be irradiated are wholesome, and that adequate meat refrigeration facilities exist.

The Interdepartmental Committee on Food Irradiation, composed of members of various Federal agencies, including the Departments of Commerce, Agriculture, and Energy, meets once a year to discuss food irradiation research. The Committee's mission is to facilitate coordination of irradiation research among Federal agencies and private industry and to help in transferring technology from the Government to the private sector.

INTERNATIONAL FOOD IRRADIATION ACTIVITIES

Foreign research and development in food irradiation is being done both by many individual countries and by the International Project in Food Irradiation. The Project was established because food preservation through irradiation offered new opportunities for increasing the world food supply by avoiding the losses sustained during storage and distribution. Irradiation was also expected to greatly reduce the use of chemical preservatives and pesticides. The Project has sponsored wholesomeness testing of food items preserved with low doses of ionizing radiation, including wheat, wheat products, potatoes, fish, spices, rice, and mangoes.

The research of individual countries has generally involved low-dose irradiation of fruits and vegetables. Today 19 countries have given various types of acceptance to 24

different irradiated foods, ranging from unlimited clearance to clearances for experimental and market testing purposes. Although a large number of irradiated foods have been cleared for public consumption, very little irradiated food is being consumed worldwide.

Such international organizations as the Food and Agriculture Organization, the International Atomic Energy Agency, and the World Health Organization have jointly sponsored meetings at which food irradiation research and development were discussed.

CHAPTER 2

FOOD IRRADIATION--IS IT A PROCESS OR AN ADDITIVE?

Some food irradiation technology proponents believe that the Food Additives Amendment of 1958, which includes food irradiation in the definition of food additive, presents an unnecessary barrier to adoption of the technology. They believe that food irradiation should be classified as a process, thereby reducing the extent of testing to prove that irradiated foods are wholesome.

On the basis of our discussions with FDA and other scientists and a review of the report of an international expert committee on wholesomeness of irradiated food, we found no reason to believe that changing the definition of food irradiation in the law would have any effect on adoption of the technology. FDA told us that food irradiation would require the same extent of animal feeding and other studies to prove wholesomeness, whether it was termed a process or an additive.

FOOD ADDITIVE LEGISLATION

The Food Additives Amendment of 1958 defines "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; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under conditions of its intended use * * *." 1/

Food irradiation was included in the definition of food additive in the law because of concern that irradiated food

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1/FDA guidelines show that, with respect to irradiated foods, FDA reviews petitions for approval to determine that the foods are nutritious and safe within the meaning of the act; that is, wholesome.

might be harmful. Questions about the wholesomeness and other aspects of irradiated foods also have been raised in the 1960s and 1970s. (See app. IV.)

VIEWS OF FDA OFFICIALS AND OTHERS

Even though food irradiation is specifically included in the definition of a food additive, the same law also covers food processes, according to FDA officials. They noted that the provision "otherwise affecting the characteristics of any food" would include food irradiation, whether one called it a process or an additive. FDA scientists and officials and the Chairman, Committee on Food Irradiation, National Research Council, said that irradiation does change the characteristics of a food. Therefore, irradiation as a process would have to be adequately tested to establish its safety.

These officials and scientists from the Federation of American Societies for Experimental Biology stated that the numbers and generations of animals tested and the variety of tests performed by the Army to prove safety were reasonable and would be required whether irradiation is considered a process or an additive. The amendment, an FDA officials said, does not require that every irradiated food needs to be individually tested for safety. If the results of wholesomeness studies on representative foods or on foods from each class, such as beef, pork, and chicken, are applicable to all foods within the groups tested, the Army could petition FDA to approve other foods without extensive animal feeding studies.

FDA officials said other preservation processing techniques, such as thermal processing (canning), are allowed without extensive animal feeding studies because they were widely used before the Food Additives Amendment of 1958. The long experience gained from thermal processing use before January 1, 1958, indicated that it was generally considered safe. FDA officials agreed that this process also falls within the definition of food additive, and, if it were introduced after the implementation of the amendment, extensive animal feeding studies would be required to establish its safety.

FDA views are also consistent with those expressed by a group that prepared a study at the request of the Secretary of the Army on the status and progress of the program. That group concluded that FDA could not and should not be directly pressured to shorten or reduce the wholesomeness testing requirements. According to the group's study, the Army is responsible for proving the wholesomeness of irradiated foods.

INTERNATIONAL VIEWS ON ANIMAL TESTING

In September 1976 the Food and Agriculture Organization/ International Atomic Energy Agency/World Health Organization Expert Committee on the Wholesomeness of Irradiated Food defined irradiation as a physical process for treating foods and, as such, is comparable to heating or freezing foods. The Committee recognized that the unique feature of irradiation is the particular type of energy employed and that this feature had aroused special attention.

The Expert Committee believed that the approach needed in the toxicological evaluation of the wholesomeness of irradiated foods differed from that used in the safety evaluation of chemicals. In the case of food additives or pesticide residues in food, their levels are exaggerated, when the foods are fed to test animals, in determining an acceptable daily intake level. The Expert Committee believes it impractical to greatly exaggerate the feeding levels of irradiated foods in animal studies beyond a modest degree or to greatly increase the radiation dosage much beyond that used in practice because either practice gives rise to effects which are not relevant to the toxicological potential of the irradiated foods. The Expert Committee noted that irradiation added nothing to the food and, therefore, is a process requiring a different approach.

The Army's approach in its toxicological evaluation of the wholesomeness of irradiated foods is consistent with the recommendations of the Expert Committee. Feeding levels of irradiated foods in animal studies are not exaggerated, nor is the irradiation dosage greater than that expected to be used in practice. The Expert Committee, although recognizing irradiation as a process rather than an additive, still believed it was necessary to carry out animal feeding studies to establish the safety of irradiated foods. The traditional multigeneration studies, extending over four generations in one species, was considered necessary for evaluation. The Expert Committee also acknowledged that it may prove possible in the future to base an evaluation of the wholesomeness of irradiated foods on the accumulated knowledge of the chemistry and products of radiolytic reactions, toxicological studies already performed, and compositional analysis of the foods in question.

CHAPTER 3

PROBLEMS WITH ANIMAL FEEDING STUDY CONTRACTS SERIOUSLY HAMPER ARMY'S FOOD IRRADIATION PROGRAM

The Army has been unsuccessful in obtaining FDA approval of irradiated meats because of stringent FDA testing requirements and the Army's failure to produce evidence to convince FDA that irradiated meats are safe. Some Department of Defense and Army officials are skeptical about whether FDA will ever approve irradiated meats.

FDA has taken a conservative position in reviewing food additive petitions, including those for irradiated foods. In 1963 FDA approved an Army petition for irradiated bacon on the basis of summaries of safety data submitted with the petition. In 1968, after looking more closely at the supporting data and determining that it failed to establish safety, FDA rescinded the approval. The Army therefore withdrew the ham petition it submitted in 1966 because it was based on the same data as the bacon petition.

Although the Army contracted with private laboratories for new animal feeding studies on beef, chicken, ham, and pork in the 1970s, it has not petitioned FDA for approving irradiated meat. A major reason for this is that two of the three contracts for animal feeding studies have been declared in default by the Army because of numerous contractor deficiencies, including missing records, failure to do tests required in the contracts, and inaccurate reporting. The Army lost about $4 million on these two defaulted contracts and 6 years of feeding study data.

Army officials visited the defaulted contractor each month for 6 years during the contract periods but failed to identify the numerous testing deficiencies. Also the Army did not pay enough attention to the deficiencies noted in an FDA investigation of that contractor, Industrial Bio-Test Laboratories, Inc. As a result of the problems experienced on the animal feeding study contracts, the Army has intensified its monitoring of its remaining animal feeding study contract for irradiated chicken.

ANIMAL FEEDING STUDIES--A KEY ELEMENT IN PETITION TO FDA

Animal feeding studies are an important part of the petition to FDA for approving irradiated foods. Through these studies, the Army seeks to show that irradiated foods are safe (free from toxic chemicals, not cancer causing, etc.) and nutritious.

The Army has conducted three phases of animal feeding studies. In phase one, from 1954 to 1959, animals were fed 54 low- and high-dose irradiated foods for about 90 days. In phase two, from 1956 to 1965, the long-term effects of feeding 22 low- and high-dose irradiated foods to rats, dogs, and mice were tested. During the first two phases, the Army spent about $6.1 million. The Army's third phase, started in 1971, involved renewed long-term high-dose studies using beef, pork, ham, and chicken. As of April 1, 1978, the Army had spent about $4.7 million on third-phase studies.

In July 1962 the Army petitioned FDA, seeking approval of irradiated bacon. FDA approved the petition in February 1963, mainly by reviewing the summaries of the petition data but rescinded this approval in 1968 after looking more closely at the supporting data. In 1968 the Army withdrew a petition for irradiated ham, which had been submitted to FDA in 1966.

FDA rescinded its approval of bacon because it believed the Army's petition had not proven that irradiated bacon was safe. FDA cited the following problems in the animal feeding studies: increased rat mortality, slight weight loss, and possible increased development of tumors. Major deficiencies in the way some experiments were conducted and designed were also noted. The Army, however, was still convinced that irradiated foods were safe.

The Army's ham petition used the bacon data as support and data obtained from the feeding of irradiated pork to animals. The Army and FDA had previously agreed that feeding bacon and pork to animals would be sufficient because ham and bacon are a part of pork. Because of the problems FDA found with the bacon data, the Army withdrew its ham petition about the time the bacon approval was rescinded.

Because of congressional interest in the program, the Army, in February 1970, reinitiated wholesomeness studies on irradiated foods. The new studies provided for a two-generation, 3-year feeding test with dogs and a four-generation, 2-year feeding test with rodents. The Army's testing protocol for its animal feeding studies was reviewed by FDA and officials from the National Research Council, National Academy of Sciences. These studies are essential to determine whether the animals

--reproduce normal and healthy offspring,

--suffer from protein and vitamin deficiencies,

--develop malformed or abnormal body parts,

--have normal weight gains and lifespans, and

--are more prone to cancer or other diseases during their lifespans.

The animal feeding tests involved studies on beef, ham, pork, and chicken. The Army contracted with Industrial Bio-Test Laboratories, Inc. (IBT), of Northbrook, Illinois (a subsidiary of Nalco Chemical Company), for the beef and ham-pork studies and with Research 900 (a division of Ralston Purina Co.) for the chicken study.

Item	Contract duration	Type of contract	Contract amounts	Amount paid as of 4/1/78
Beef	a/3/ 1/71 to 10/ 7/77	Fixed price	$3,458,693	$3,113,976
Ham and pork	6/ 1/76 to 10/ 7/77	Cost plus fixed fee	$4,693,965	$ 798,038
Chicken	6/ 1/76 to 9/30/80	Cost plus fixed fee	$2,547,395	$ 802,511

a/Includes contract extensions.

An official of the Surgeon General's office told us that the quality of Research 900's work on the chicken contract was generally good and that the animal feeding study was progressing satisfactorily. In January 1977 and again in January 1978, however, Research 900 experienced a problem. Rat offspring fed both the irradiated and the control diets were dying young. Army officials have been unable to identify the reason for the early deaths but do not believe the deaths were caused by the use of irradiated chicken.

A Surgeon General official estimates that, because of these problems and the necessity to restart rodent feeding studies, the chicken feeding contract, which is scheduled to end September 30, 1980, will probably be extended 9 months to a year.

Contract defaults hamper Army's meat petitions to FDA

Under the terms of the beef contract, IBT was expected to provide the Army with a final report on December 31, 1976. About September 1976 IBT officials requested a 6-month extension to complete their tissue slide readings and to prepare their final report. Because of the magnitude of the beef feeding study, the Surgeon General granted the extension.

On June 14, 1977, the President of IBT met with Army officials to discuss problems the company was having with the beef feeding studies. At this meeting, and through subsequent discussions with IBT officials, Surgeon General representatives became aware of serious problems with the beef study and the ham and pork study. Because of the problems, the Army, on October 7, 1977, declared IBT in default on both contracts.

The Army said that, during the June 1977 meeting, it learned of many problems with IBT's performance under the beef contract. These included missing records, unallowable departures from contract testing protocol, poor quality work, and incomplete disclosure of information on the progress of the studies. Specifically, the Army found that:

--Body weight and food consumption data were missing on some rats and mice.

--An IBT quarterly report incorrectly stated that all dogs were killed, when, in fact, 17 dogs were still alive. Further, in June 1975 the contractor took these 17 dogs off the test diets and put them on standard dog chow without informing the Army. These actions violated contract testing protocol and no longer permitted valid comparisons between control and test groups.

--IBT initiated its readings of animal tissue slides in March 1972. In violation of the contract, the contractor failed to record readings for every slide examined but, instead, recorded readings on positive slides only, such as those which disclosed cancerous tumors. This action prevents a proper evaluation of test results.

--The work on collecting semen samples at least five times on each of 50 dogs was initiated in November 1976, but as of June 1977 only one sample had been collected from each of 27 dogs, and only some of these samples were usable.

--Numerous other required experiments either were not completed or were improperly conducted.

After the June meeting, a Surgeon General official, through discussions with IBT, determined that the ham-pork study had serious deficiencies, including violations of testing protocol and poor scientific techniques and judgment. For example, IBT:

--Initiated dog reproduction studies in September 1976 but did not start with a large enough parent generation to produce the contractually required 300 first-generation dogs. As a result, first-generation offspring were born from 2 to 9 months apart. This relatively long time between births made it difficult for IBT to compare the dogs in terms of weight history, developmental processes, etc. IBT failed to put the dogs on the test diets immediately after they were weaned and in some cases planned to wait a year or more. The Army considers these examples of poor scientific techniques.

--Initiated mice feeding studies in December 1976 with different housing conditions for male and female mice. The Army believed this was poor scientific judgment because the housing conditions made it difficult to compare the effects of the diets on the sexes.

--Experienced problems in February and March 1977 with many of the first-generation rodents dying relatively young. The problem was thought to be caused by the nonirradiated basal diet. IBT switched the diet of existing rodents on test to a standard rodent chow rather than start new rodents on test. The Army believed IBT used poor scientific judgment by feeding the new diet to the surviving first-generation rodents rather than new rodents.

--Encountered health problems in March 1977 with male mice, which were not reported to the Army.

According to the Defense Acquisition Regulations, the Government is required to give a contractor the opportunity to correct deficiencies, such as those cited above. Surgeon General officials corresponded with and made followup visits to IBT during the 3 months after the June meeting to determine whether the contractor had corrected the deficiencies. IBT had not corrected the deficiencies, and it was unable to prepare a final beef feeding study report. The Army declared IBT in default on both contracts in October 1977. Army officials have concluded that the IBT animal feeding study data for beef, ham, and pork is unusable to support a petition to FDA for approving these meats.

According to the Army the prospects of recovering the $3.9 million paid to IBT are slim. Army officials believe the maximum that could be recovered of the $798,038 paid to IBT on the ham and pork contract would be the fee of

$52,208. An Army contracting official said the Army could sue to recover in reprocurement costs the $3,113,976 paid to IBT on the beef contract in the unlikely event that the Army contracts with another firm for an identical study.

The Army's default of the two IBT contracts and the necessity to restart rodent feeding studies on the Research 900 contract has significantly affected the time frames the Army initially established for submitting petitions to FDA. The initial target dates for submitting the beef and ham-pork petitions to FDA were 1977 and 1981, respectively. These two studies would have to be redone. The chicken study, originally expected to be submitted to FDA by 1981, has been pushed back to 1982.

Army monitoring failed to disclose deficiencies

The Army's monitoring of the beef and ham-pork feeding contracts consisted of 1- or 2-day visits to IBT each month during the contract periods (6 years for the beef contract). These visits were made by a veterinarian in the Surgeon General's office, accompanied by a Natick official. The purpose of the visits was to determine the status and progress of animal testing studies, identify and resolve problems, and ensure that the contractor was using scientifically sound testing methods and complying with contract provisions. However, during these visits, the Army monitor failed to find the numerous IBT testing deficiencies which eventually led to default.

Several Army consultants visited IBT from 1971 to 1977 to assess the adequacy of some of its procedures. On one of these visits, a team of scientists from the National Research Council spent several days resolving problems with the rodent diet and observing IBT tests using this diet. Also pathologists from the Armed Forces Institute of Pathology, during 22 visits to IBT, evaluated the firm's practices in reading and analyzing pathology slides. However, the pathologists only evaluated IBT's practices in analyzing positive slides rather than all slides, positive and negative. An outside nutritionist under contract to the Army accompanied the Surgeon General's monitor on several visits and assessed the contractor's practices in diet preparation and diet nutrient analyses; he found no deficiencies.

In January 1976, about 6 months before the award of the ham-pork contract to IBT, an Army Source Selection Board, responsible for evaluating seven prospective bidders on this

contract, rated IBT the highest. Factors considered by the Board included the adequacy of IBT's animal testing facilities and equipment, previous experience, personnel, and computer capabilities. The Board's review, however, did not identify any deficiencies in those areas.

In April 1976, before the award by the Army of the ham-pork feeding contract, FDA identified deficiencies in IBT performance similar to those which eventually led the Army to default the IBT contracts. Army officials told us they were not aware of FDA's investigation at the time the ham-pork contract was awarded in June 1976. The FDA investigation involved IBT performance under contracts with FDA and certain private companies which used IBT data in petitions to FDA.

A number of newspaper articles, starting in July 1976, reported serious deficiencies in IBT's testing practices. These disclosures were based on FDA's investigation of IBT. The deficiencies reported included failure to do laboratory tests which IBT reported as done; improper recordkeeping; false and incomplete reporting of test results, including animals reported as sacrificed that were still alive; and poor quality testing. The Surgeon General's representative responsible for monitoring IBT at the time of the initial newspaper disclosures told us that he was concerned about the deficiencies. However, he accepted IBT's statements that these deficiencies were gross misunderstandings by FDA investigators and others and continued to believe the Army's studies were progressing satisfactorily. He did not contact FDA to determine the results of its investigation of IBT.

As early as August 1973, a Natick representative, in a visit to IBT, observed that the laboratories, staff, and supervision of laboratory work at IBT was barely adequate for the feeding studies. According to this official's trip report, IBT officials responsible for the feeding studies were unable to answer many of his questions about the animal testing. The Surgeon General's representative who was responsible for monitoring IBT at that time told us that he did not consider these observations serious enough to warrant further study.

IBT officials told us that they had not adequately managed the Army's animal feeding contracts because of their heavy workload and that the monitoring done by FDA and private firms on their respective feeding study contracts with IBT was generally similar to the Army's monitoring. Even though IBT officials agreed that required reports were not prepared and not sent to the Army on time, they said the Army's failure to ask for these reports was as bad as IBT's not preparing them.

Army intensifies its contract monitoring

According to Surgeon General officials, their monitoring was not adequate to disclose the deficiencies that led to default. They stated that in the early 1970s the Army relied on IBT's excellent reputation as a scientific testing laboratory. As a result of the IBT defaults, the Surgeon General's office recently assigned a military veterinarian with a background in laboratory animal colony management to monitor Research 900's performance. The veterinarian will work part time at Research 900, and his duties will include observing experiments to ensure contractor compliance with testing protocol and good scientific practices and sampling contract data. A Surgeon General representative still plans monthly visits to the contractor to examine feeding study data, and, as needed, outside consultants, such as nutritionists and pathologists, will also be used.

SKEPTICISM OVER POSSIBLE FDA APPROVAL

Some Army and Defense officials said they were skeptical that irradiated meats would ever be approved by FDA. They doubt whether the public will accept irradiated foods and whether commercial firms will use food irradition technology. According to an FDA official, his agency received petitions after 1971 for only two food additives--an artificial sweetener and an antioxidant, 1/ which testing protocol he considered comparable to those used for the irradiated meat feeding studies. FDA approved one, but it took the petitioner 4 years to satisfy FDA of its safety. FDA approved the other additive but is now holding the approval in abeyance because of questions raised about the validity of the data supporting the petition.

An FDA official said his agency would probably scrutinize future food additive petitions more closely, including those the Army would submit for irradiated meats. Another FDA official explained that the science of toxicology is becoming more complex due to advances in the science and that more time and money is required for the toxicological studies. For these reasons, one Defense official believed that continuing the irradiation program would be a waste of money. An Assistant Secretary of the Army, however, believes that it is important to arrive at a definite conclusion on irradiated foods so that this long and costly program does not end inconclusively.

1/Substance that prevents oxygen from combining with fats, thus retarding food spoilage.

ADDITIONAL TIME AND MONEY TO COMPLETE ALL ANIMAL FEEDING STUDIES

Assuming that the animal feeding study on irradiated chicken continues to progress satisfactorily and that FDA has no problems with the supporting data, FDA approval of irradiated chicken might be received by September 1983. The Army has estimated that, for fiscal years 1979-83, the cost to complete the chicken study, including in-house research efforts to support a petition to FDA, will be about $10 million. Total estimated costs of completing the chicken study and restarting the beef and ham-pork studies to obtain approval by FDA range from $28 million (Natick estimate) to $47 million (Army headquarters estimate).

CHAPTER 4

ARMY FOOD IRRADIATION RESEARCH SHOWS PROGRESS IN MANY AREAS

Research conducted by Natick, which is currently funded at $3 million a year, has shown progress in acquiring the knowledge needed in support of petitions to the FDA for approving irradiated meats. Natick officials believe that the Army has enough research data, except for animal feeding studies, to support its petitions to FDA. Additional laboratory research is justified, according to one Natick official, because the issue of safety is not absolute and improvements are always needed in packaging and other aspects of the technology.

Because FDA has not yet approved any irradiated meats and because of Natick's assessment of the knowledge, which has been accumulated from 25 years of research, a reevaluation of the need for continuing the research at the $3 million level is in order.

STATUS OF NATICK'S RESEARCH

Natick's research includes radiation chemistry, microbiology, packaging, processing technology, and irradiation technology. The estimated costs of the reseach are about $3 million and $3.2 million for fiscal years 1978 and 1979, respectively. This research supports the animal feeding studies being coordinated by the office of the Surgeon General.

Radiation chemistry

Radiation chemistry research concerns possible harmful effects of chemical changes in the food caused by the irradiation. Research has been directed at understanding the chemical reactions taking place in irradiated meats. Objectives include determining whether

--irradiation causes minor but acceptable chemical changes in the meats and

--information developed would allow extrapolation from approved irradiated meats to untested meats in the same generic class.

Natick believes that sufficient radiation chemistry research has been completed to demonstrate to FDA that no harmful chemical effects are produced in irradiated beef, ham,

pork, and chicken. Natick's future research intends to focus on how irradiation affects the chemistry of various types of proteins, such as muscle tissue and connective tissue, and the various products formed from the fats in the meats after they have been irradiated.

Microbiology

Microbiological research concerns the ability of irradiation to destroy all potential disease-causing and spoilage micro-organisms in meats. Since many such micro-organisms exist in food, Natick officials believe continuing research is necessary. This effort will be directed at the potential radiation resistance of various bacteria.

A Natick official acknowledged, however, that enough microbiological tests have been completed to demonstrate to FDA that irradiation destroys the harmful bacteria in irradiated beef, ham, pork, and chicken, and the irradiated meat would be free of bacterial spoilage and any other microbial problems.

Packaging

Natick's packaging research seeks to demonstrate that packaging material is not absorbed into irradiated beef, adversely affecting its wholesomeness, and to improve the quality of irradiated meat packages, including cans and flexible pouches.

Unlike the other sections of a petition to FDA (microbiology, processing technology, radiation chemistry, irradiation technology, and animal feeding studies), the packaging petitions can be submitted to FDA for separate approval. FDA has approved certain flexible packaging materials to be irradiated with a gamma source; however, it has not yet approved cans for use in the irradiation of meats.

According to a Natick official, Natick's research is directed at obtaining FDA approval of a wide variety of packaging materials to give private industry a choice of containers in commercial meat irradiation. The official believed that Natick's testing has demonstrated the safety of irradiated meat packaging. Continuing research efforts will focus on developing packaging materials with greater durability that can withstand varying temperatures, are less costly, and require less energy to manufacture.

Processing technology

Processing technology refers to the entire irradiation process, from slaughtering the animal to cutting the meat to the desired shape and packaging, freezing, and irradiating it. Natick has developed standard irradiation sterilized beef, ham, pork, and chicken products which, Natick officals believe, are highly acceptable and have no off-flavor. Research has been done using meats from entire animal carcasses to prove that wholesomeness generally is applicable to all meats, not just special cuts. Continuing research would be directed at improving the processing technology for selected individual meat ration items and developing acceptable irradiated luncheon meats.

Irradiation technology

Natick officials believe they can support irradiation technology sections of the beef, ham, pork, and chicken petitions to FDA. The term "irradiation technology" includes many factors, such as defining irradiation, developing the facilities or equipment used in irradiation, and determining the basic effect of irradiation on food. It also encompasses how the irradiation is controlled and measured, how facilities can be administratively controlled to ensure safe use, and how to demonstrate that no radioactivity is produced in food by ionizing radiation. A Natick official said that all basic knowledge in the area had been acquired, including preparation of regulations for controlling a food irradiation industry and for determining that irradiation produces no radioactivity in foods.

Continuing research efforts will focus on developing more accurate means to measure radiation absorbed in food.

ACCEPTANCE AND EDIBILITY OF IRRADIATED MEATS

The Army has been conducting tests since 1953 with civilian and military personnel to demonstrate that irradiated foods had acceptable sensory chacteristics, such as color, odor, and flavor. The use of consumer acceptance panels is a traditional approach for comparing the sensory chacteristics of one substance with another.

Civilian acceptance tests, started by the Army in 1953, generally involved 30 to 40 persons per test. The Army tested such foods as irradiated chicken, pork, ham, bacon, bread, and potatoes. In most of these tests, consumer panels compared irradiated foods with fresh or frozen foods while, in other tests, consumer panels evaluated only the irradiated foods.

Irradiated meats were rated slightly lower than fresh or frozen meats but achieved high enough scores to make them acceptable for military rations. The Army has continued civilian acceptance tests at Natick to provide FDA with additional evidence that irradiated meats have acceptable sensory characteristics.

The Army conducted 19 acceptance tests from 1958 to 1970 on troops using various irradiated products, including beef, pork, ham, bacon, chicken, fish, bread, and potatoes. Generrally, two groups were used in each test: one rated the irradiated and the other rated nonirradiated fresh, chilled, or frozen foods. Results in these tests were similar to those in the civilian acceptance tests.

A Natick official said the Army discontinued troop acceptance tests in 1970, realizing plans to introduce irradiated foods into the military ration system would be delayed because of the earlier unfavorable FDA decision on irradiated bacon. Troop acceptance tests would be restarted when and if FDA approved irradiated foods.

An FDA official who tasted irradiated meats in the 1960s believed that these meats had an off-taste. He commented that the irradiated meats recently sampled tasted better. A reason for this improved taste is that meats have been irradiated since 1965 in a frozen state rather than at room temperature. Chemical reactions that would alter the flavor and odor of the meat are eliminated when the water in the meat being irradiated is frozen. The Army noted, in acceptance tests, that meats irradiated while frozen are markedly more acceptable than those irradiated at room temperature.

CHAPTER 5

IMPACT OF IRRADIATED MEATS ON MILITARY RATIONS UNCERTAIN

The justification in using irradiated meats in military rations is that they will provide wholesome, good-tasting, high-quality, shelf-stable meat that can be stored without refrigeration for extended periods. Traditional thermal processing, such as canning, provides a limited food variety, and chilled and frozen meats are expensive to preserve because of the refrigeration needed. However, recent improvements in thermal processing technology (tray pack thermal sterilization) and the Army's practice of providing soldiers with fresh or frozen meats whenever possible because of their high acceptance, raise doubts about the degree to which irradiated meats would affect the military ration system.

The most recent comprehensive cost-benefit analysis showed that savings would have occurred had irradiated meats, rather than frozen meats, been used in Vietnam because refrigeration would have been eliminated during the trip from the United States. For other locations studied, however, other methods of preserving meats were generally found to be less costly. None of the cost-benefit studies are recent enough to account for the increased energy costs in the last 10 years.

MILITARY RATION SYSTEM

There are two categories of military rations. The first is the A-ration which is the military's standard perishable food item. The meat and poultry A-rations are purchased fresh or frozen and are stored and preserved in refrigerated food lockers until used. The military's objective is to provide troops with A-rations whenever possible.

The second category is the B-ration, which is designed to support combat troops operating away from A-ration supply lines. The meat and poultry components of the B-ration are preserved by traditional thermal processing or by freeze-drying. Both methods result in foods that can be packaged in cans or heat-sealable aluminum foil containers and stored in warehouses for long periods without refrigeration. This feature, called shelf stability, distinguishes the B-ration from the A-ration. During fiscal year 1977 about 91 percent of the red meat and poultry centrally purchased by Defense were A-ration items and 9 percent were B-ration items.

B-rations are generally used for feeding large numbers of troops in the field where kitchen facilities are available but refrigeration is not. B-rations also include individual rations, which are used to feed soldiers in tactical situations, and specialty rations, such as the Long Range Patrol Packet and the In-Flight Food Packet, which are processed and consumed in relatively small quantities. According to Natick officials, thermal processing and freeze-drying preservation techniques have limitations which could be solved by irradiation.

Thermal processing limited in variety and quality of sterilized meats

In thermal processing, meat or poultry must be chunked, diced, sliced, or sectioned and then vacuum packed with liquid in cans to facilitate the heat transfer essential to preserving the meat. After canning, the meat product is cooked to a temperature of about 250° F.(121° C.). The cooking times vary significantly with the can size. After cooking, the product is cooled, labeled, and stored. The process produces a well-done product with a canned flavor, a soft texture, and a distinct taste, readily identifiable as a fully cooked item. (Fig. 3 shows irradiated pork loin and thermally processed pork loin.)

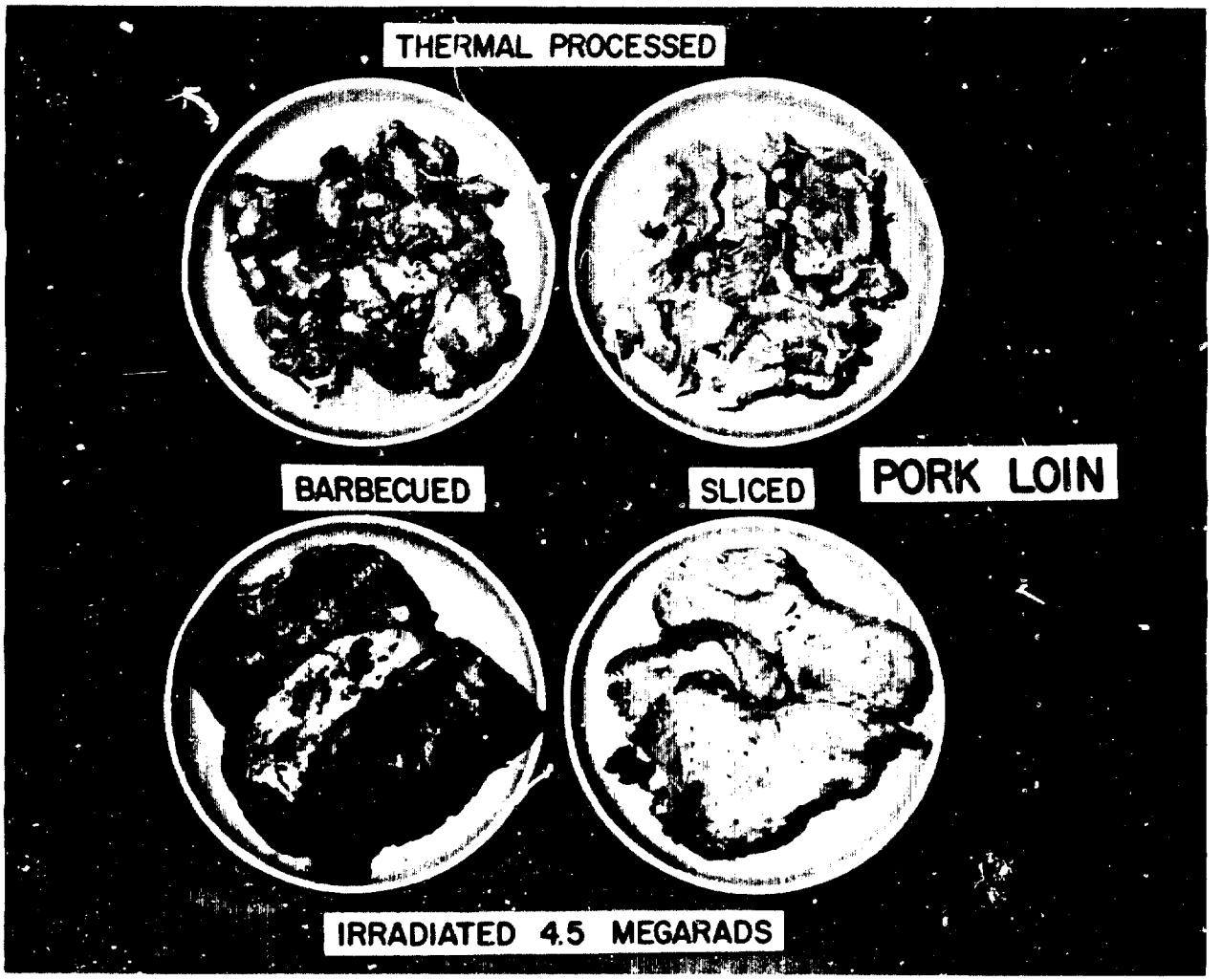
Another problem associated with eating thermally processed canned foods is monotony. Natick officials stated that, in field situations, troops get tired of eating canned foods for long periods and may eat less. This would affect nutritional intake and could adversely affect combat effectiveness. Recognizing this, Army headquarters officials, including those from the office of the Surgeon General, have recommended that, wherever pratical, troops should not be maintained solely on canned rations for more than 10 days.

Natick officials stated that, unlike thermal processing, irradiation can preserve a whole roast beef, pork roast, beef rolls, pork rolls, chicken rolls, and fried chicken. Thermal processing cannot be used for such items because the required high cooking temperature produces an overcooked unacceptable product.

Improvements in thermal processing technology offer greater variety of food items

Natick has developed an improved thermal packaging configuration called tray pack, which is designed exclusively for mass feeding situations. This method uses a pan-shaped container rather than a can. It reduces cooking times 50 to 75

FIGURE 3



COMPARISON OF THERMALLY PROCESSED BARBECUED AND SLICED PORK LOIN WITH COMPARABLE IRRADIATED PORK LOIN

Source: Natick Research and Development Command

percent and improves product quality. In addition, many more food items can be processed with tray pack than with traditional thermal processing methods which, because of long cooking times, compress items, like stuffed peppers or Swiss steaks, and destroy the texture of meats and vegetables. For example, with tray pack more meats, such as sliced roast beef, beef burgundy, and Italian sausages, would be available. (Fig. 4 shows a sample of meat items processed using tray pack.) Tray pack technology does not yet apply for individual rations.

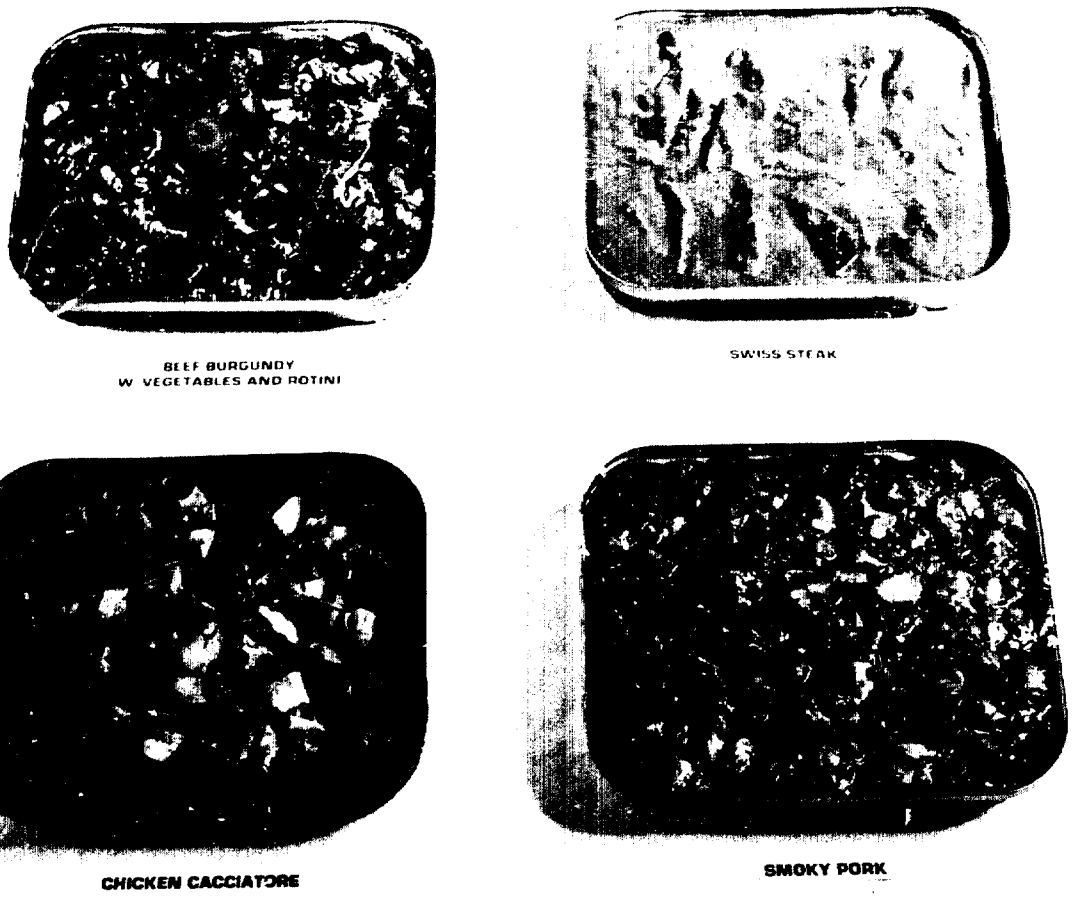
Although tray pack should improve the variety and quality of thermal processed items, it still has limitations. The shallow tray cannot hold such items as a whole roast beef, roast pork, hams, or beef or chicken rolls. Also meat items cannot be cooked medium or medium rare. The need for liquid as a heat transfer agent also prevents use of tray pack to process such items as fried chicken. Natick officials have identified all of these items which cannot be processed using tray pack as foods that can be processed using irradiation. According to one official, foods processed by tray pack are expected to be introduced into military rations within the next 3 years.

Freeze-drying is energy intensive and expensive

In freeze-drying, water or moisture is removed from the meat when frozen, therby preventing the food from spoiling. Meats or poultry are diced or cut to a thickness of less than one-half inch to minimize the processing time and cost and to maintain product quality. After cutting, the product is frozen to minus 40° F. (minus 40° C.), which takes 3 to 4 hours, and then freeze-dried for about 16 to 18 hours in a vacuum chamber which removes all moisture. The dehydrated product is compressed and sealed in a can or flexible pouch. The result is a virtually spoilage-proof meat or poultry item that has been reduced in weight and volume, offering a logistics advantage to the military.

According to a Natick official, dehydrated foods were used by troops during the Vietnam conflict, particularly on long-range patrols. Another official said military users had praised these foods. Besides continuing the use of freeze-dried foods for long-range patrol rations, the military has introduced freeze-dried foods in the new Meal, Ready-To-Eat combat ration and is developing an assault packet containing freeze-dried foods for 2- to 3-days' use. According to a Natick official, in tactical situations where weight is a critical factor, freeze-dried foods will have a significant impact.

FIGURE 4



NEW FOOD ITEMS THAT CAN BE PROCESSED BY IMPROVED THERMAL PROCESSING METHOD CALLED TRAY PACK

Source: Natick Research and Development Command

Although freeze-drying has tactical advantages, it cannot make available whole roasts, hams, and beef and chicken rolls, or fried chicken because of the thinness restrictions. In addition, the time and energy requirements to blast freeze and then dehydrate foods make this an expensive process. Defense is paying almost $9 a pound for freeze-dried beef steak, compared to $1.57 a pound for frozen oven roast and $3.32 a pound for frozen grill steak.

POTENTIAL OF IRRADIATED FOODS IN MILITARY RATIONS

Irradiation can resolve or alleviate the limitations of current processing methods, according to Natick officials. Also irradiated meats can improve the quality and variety of canned meats presently preserved using thermal processing. These officials believe that, logistically, irradiated meats would have advantages over fresh-chilled and frozen meats which require constant refrigeration, particularly in field feeding situations where the potential for spoilage is greater and where refrigeration costs are higher.

The sterilization of meats and poultry using irradiation is similar to the thermal processing techniques in the pre-preservation work required. Both procedures require the meat to be trimmed, inspected, and weighed. Salt is added to aid in the retention of natural juices, and the meats must be shaped to fit the container (can or flexipouch). Thereafter, the irradiation preservation procedures are different.

Before canning, the meat must be precooked to about 167° F. (75° C.) to inactivate enzymes that would destroy the meat fiber because irradiation itself will not destroy them. After canning, the meat must be frozen to about minus 35 F. (minus 37° C.) to minimize flavor changes during the irradiation process. After freezing, the meat and poultry is exposed to 4 to 6 million units of absorbed radiation, depending on the product. The canned product is then thawed, labeled, packaged, and stored.

With irradiation processing, almost as many processed foods could be made available as in a fresh or frozen state. For example, whole roasts and hams, medium-rare steaks, chicken rolls, sausages, pork chops can be prepared using irradiation preservation techniques. According to Natick officials, irradiated foods can overcome the monotony problem associated with other processed foods because they are very similar in quality and texture to fresh and frozen foods. Because of this similarity, irradiated meats could be used over longer periods without the need for fresh or frozen foods.

The military services have not been surveyed recently to determine if they have special needs that irradiated meats and poultry can meet. To date, Navy and Air Force officials have identified some instances where irradiated meats could be used; for example, aboard submarines and as emergency crash rations on flights. Astronauts ate irradiated meats during the joint U.S.-Soviet Union Appollo Soyuz space mission in 1975. (Fig. 5 shows irradiated meats such as those consumed during that mission.)

Natick officials believe that, when irradiated meats and poultry are approved and made available, each of the services, from an economic, logistic, and quality standpoint, will find uses for them. During the 1960s the Army took the position that it would use irradiated meats to replace or partially replace frozen or thermally processed meat counterparts. The Defense Food Planning Board 1/ will not identify how irradiated foods can be used in the military ration system until FDA approves them. The Chairman of the Board believes that, once FDA approves irradiated meats and poultry, the services will probably find uses for them.

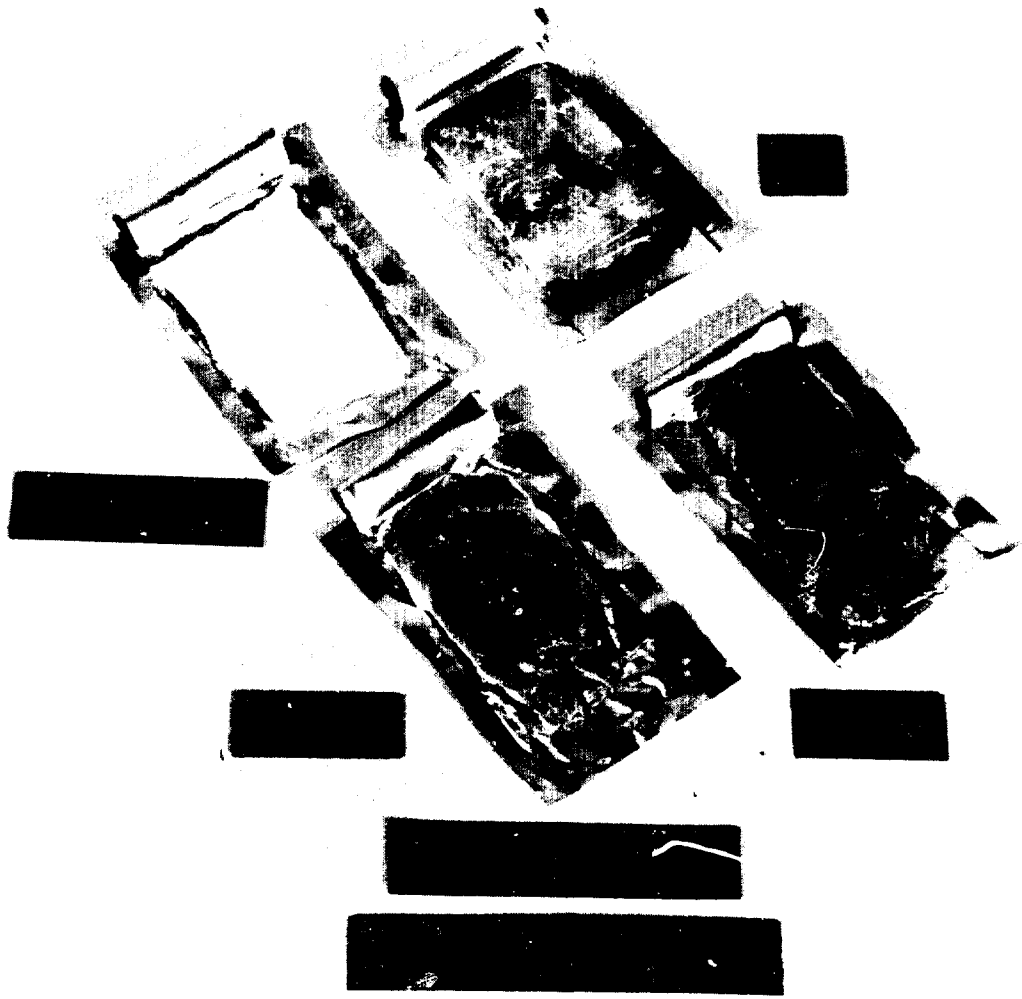
Other advantages in using irradiated meats

The greatest potential for irradiated meats to improve military rations appears to be in mass field feeding situations. As mentioned earlier, tray pack's greatest potential is also in this situation. The areas of improvement differ, however. Irradiation processed meats produce dry-packed meats without sauces, gravies, or vegetables which tray pack can offer.

According to Natick officials, irradiated foods can be tailored for use in the individual combat packet. However, this packet contains a canned meat item which is the major component of the meal. Generally the meat is in combination with vegetables and gravy. The irradiated packet will contain only the meat item. If irradiated meats were introduced into the individual combat packet, the Army would have to give some thought to its redesign.

1/Responsible for developing and maintaining recipes, determining the food items to be used in the Armed Forces food programs, initiating request for development of new food items, and packaging and developing a standard menu service to support varying operating conditions and requirements.

FIGURE 5



IRRADIATED MEATS CONSUMED ABOARD THE APOLLO–SOYUZ SPACE FLIGHT

Source: Natick Research and Development Command

IRRADIATED MEATS OFFER COST SAVINGS IN SOME CASES

We reviewed available comparative cost studies for high-dose irradiation of meats. Many of the studies are outdated. None of the studies consider increased energy costs in the last 10 years. The most recent comprehensive cost-benefit analysis was prepared in 1972 by the Department of Commerce. The study, based on 1966 to 1968 data, compared the processing and distribution costs for certain items 1/ preserved by irradiation, thermal processing, dehydration, and freezing. The study compared what such costs would have been in three locations: Vietnam; Germany; and Fort Gordon, Georgia.

The Commerce study showed that irradiated meats generally would have cost more than either frozen or thermally processed meats. However, where transportation costs, storage costs, and other factors are considered, the study shows that, in some cases, certain irradiated items might cost less. For example, the study reports that:

--The United States would have saved about $18 million using irradiated, instead of frozen, items in Vietnam during 1968. All irradiated items studied showed a saving.

--A $2.3 million saving would have been realized by substituting irradiated-canned for thermally processed items in Vietnam. Three of the five items studied showed a saving.

--In Germany $2.3 million would have been saved by using irradiated-canned instead of frozen bacon. For all other items studied, whether frozen or thermally processed, no saving would have been realized.

--$1.1 million would have been saved at Fort Gordon by substituting irradiated-canned for frozen bacon. Like Germany, there would have been no saving if other irradiated items had been used.

--All three locations would have saved by using flexible-packaged irradiated beef and shrimp instead of their dehydrated counterparts.

1/The meats compared in the study were beef, ham, chicken, pork, bacon, and shrimp. Since the Army does not provide thermally processed canned pork, only frozen pork was compared with irradiated pork.

The processing and packaging costs were found to be higher for irridiated-canned or flexible-packaged meats than for frozen meats. In Vietnam, however, these higher costs were offset by the lower distribution costs for the irradiated meats.

The study also showed that the use of irradiated meat and poultry rather than thermally canned items would not have produced savings except in certain cases in Vietnam. The processing and packaging costs for thermally canned meats were lower than those for irradiated meats, but thermally canned meats generally had higher distribution costs. Only in Vietnam did the lower distribution costs for irradiated items offset their higher processing and packaging costs.

It is unknown whether in Vietnam the decision would ever have been made to substitute the less costly irradiated items for more costly frozen meat and poultry items because acceptance tests, to date, still show that fresh and frozen meats rate higher than irradiated meats.

CHAPTER 6

CIVILIAN MARKET DEMAND FOR IRRADIATED MEATS--WOULD IT BE LARGE ENOUGH TO ATTRACT PRIVATE INVESTMENT IN THE TECHNOLOGY?

Irradiation of meats may have some military and commercial uses, but the Army has little evidence that the potential demand for irradiated meats would be large enough and the profit sufficient to justify commercial firms' investing in food irradiation.

The Government generally relies on private industry to meet its requirements for military items, including food. The Army, consequently, recognizes that an adequate civilian production base is required before military ration requirements can be met. Meat irradiation sterilization facilities, exclusively for military use, would not be economical because of fluctuations in military demand; that is, periods of relatively low military activity to full mobilization. A Department of Commerce report prepared for the Army concluded that private funds would not be invested in facilities to irradiate foods for military use alone in the absence of a substantial and expanding nonmilitary market.

Other than using inquiries to measure commercial interest, the Army has not identified and estimated the potential commercial market for irradiated meats. Meat and food organizations we contacted either showed a general lack of information or expressed mixed views on the potential benefits of either high- or low-dose food irradiation. Their impressions of the quality of irradiated meats were based on outdated irradiated meat tests, which indicated odor and flavor problems, or on second-hand information. On these bases, some of the organizations believed irradiated meats would not be acceptable to their own taste panels or to consumers. Our discussions with industry representatives, however, did show that they would reevaluate the merits of food irradiation, if approved by FDA, on the basis of such factors as the quality of the product, the economics of the process, and consumer acceptability.

COMMERCIAL INTEREST UNCERTAIN

In 1972 Natick representatives visited and obtained the views of selected meat and seafood processors, retailers, and trade organizations on food irradiation. This survey showed commercial interest in irradiation, assuming that irradiated

products were approved by FDA and the Department of Agriculture, priced reasonably, guaranteed to be profitable, and accepted by consumers.

Although this survey appeared to show commercial interest in food irradiation, our review found little immediate commercial interest in the process, apparently because we did not use the assumptions used in the Natick survey. We contacted 3 of the top 10 poultry processors, 3 meat processors, 3 commercial radiation service firms, 1 food consultant, 2 meat trade organizations, and 2 professional food science and technology societies.

The three poultry processors expressed mixed views. Two believed that, if profitable, low-dose irradiation to control salmonella or extend shelf life would be beneficial to their industry. The other believed that current methods of salmonella control were adequate and that refrigerated shelf life extension was not necessary. This third processor believed the only application for irradiation would be in the high-dose area, if the shelf-stable product would be accepted by consumers. Two of the three poultry processors said they would provide irradiated chicken to the military if it were profitable.

The three meat processors also had differing views. One believed that low-dose irradiation would be useful to extend the shelf life of meats. He said he was not convinced that high-dose irradiation technology was perfected and believed the products had too much off-flavor. The second processor believed that benefits were only available from high-dose applications of irradiation for the military ration system and in underdeveloped countries. The third expressed an interest in food irradiation only in its being able to produce a nitrite/nitrate-reduced meat product. Two of the three, however, said that they would provide irradiated meats to the military if it were profitable. One processor believed that, because of the high capital investment costs--according to a Natick official, the cost could range from $2 million for a pilot plant to about $22 million for a medium-size plant--food irradiation probably would not be profitable without a Government subsidy or commercial market.

Two of the three commercial radiation service firms believed that the only commercial application of irradiation would be in the low-dose area for such uses as controlling salmonella and trichinosis. These two believed that high-dose irradiated food products would not be acceptable due to low-product quality. The third firm has a longstanding interest in both low- and high-dose food irradiation.

The food industry consultant believed that both high- and low-dose irradiation had some benefits. He said that low-dose irradiation could be used to control salmonella and sterilize spices and that high-dose irradiation could offer products, such as sterilized canned hams and canned roasts. The consultant attributed the little interest in irradiation processing to the empty promises given by Army officials over the years that FDA would soon approve irradiated foods. Since FDA has not done so, industry now believes it will never approve it.

One meat trade organization believed that the only market for irradiated meats was the military because irradiated foods would probably be expensive and consumers are slow to accept new processed food products. The other trade organization believed that only minimal interest in irradiated foods existed among its members because irradiated foods compared unfavorably with frozen or thermally processed foods. The two professional societies could not express a view because they were unfamiliar with the irradiation preservation process.

TECHNOLOGY TRANSFER ACTIVITIES

According to Natick officials, their efforts to transfer technology and stimulate commercial interest in irradiated foods have been minimal because FDA approval has not yet been obtained. They have written and presented numerous technical papers and participated in many technical conferences. Industry representatives have toured the irradiation facilities at Natick. On two occasions Natick officials visited meat and poultry processors to obtain their views on food irradiation.

During the first visit in 1972, Natick officials obtained views on high-dose applications of irradiation. During the second visit in 1977, at the request of the Interdepartmental Committee on Food Irradiation, Natick officials determined industry's interest in low-dose irradiation applications. They emphasized irradiation's potential to prevent spoilage and discoloration of fresh meats during storage and shipment even with good refrigeration. They also noted the export potential of high-dose applications of irradiation to meats for Arab countries, Puerto Rico, and South America.

CHAPTER 7

CONCLUSIONS, RECOMMENDATIONS, AND AGENCY COMMENTS

The food irradiation program, while not yet succeeding in obtaining FDA approval of irradiated meats as safe and nutritious, has made progress in advancing the state of the art. FDA's rescinding approval of irradiated bacon and advances in other food technologies caused the Army to seriously consider scrapping the program in 1970; however, congressional interest caused the Army to continue.

Extensive long-term animal feeding studies were initiated in the early 1970s as part of a renewed effort to obtain the data needed to satisfy FDA requirements. A large portion of this new effort--$4 million spent on feeding studies on irradiated beef, pork, and ham--has been wasted. The Army did not adequately review the work as it was done by the contractor, and the Army subsequently found the work to be unacceptable. The Army has recently intensified its monitoring of the remaining animal feeding study contract on irradiated chicken to ensure that the tests are properly conducted.

The Army declared the contractor in default on the animal feeding studies on irradiated beef, pork, and ham and this has had an adverse affect on the Army's time frames for obtaining FDA approval of irradiated meats. The Army believes that, if the irradiated chicken feeding study continues to progress satisfactorily, it might be able to obtain FDA approval for that item by September 1983 at an additional cost of about $10 million. Cost estimates for restarting the beef, pork, and ham animal feeding studies to obtain FDA approvals and completing work on irradiated chicken range from $28 million (Natick officials) to $47 million (Army headquarters).

After 25 years of research costing about $51 million, the Army has not introduced irradiated foods into the military rations.

LEGAL AND SCIENTIFIC BARRIERS

Food irradiation is included in the definition of food additive in the law and requires FDA approval before its public use. Satisfying FDA requirements involves extensive animal feeding studies and other laboratory research to demonstrate that irradiated foods are safe and nutritious.

Some food irradiation proponents believe that classifying food irradiation as a process, rather than an additive, in the law would reduce the extent of testing required and, consequently, facilitate commercial adoption of this

technology. We found no basis to presume that changing the definition of food irradiation in the law would speed up adoption of the technology since FDA requirements would be the same whether food irradiation is termed a process or an additive.

Some Defense and Army officials are skeptical that FDA will ever approve irradiated meats. Failure to obtain FDA approvals for meat in the past and FDA's increasingly close scrutiny of food additive petitions give some basis for this skepticism.

In spite of the problems with animal feeding studies, the Army's research, conducted and sponsored by Natick and presently funded at $3 million a year, has shown progress in acquiring knowledge of and otherwise developing the food irradiation technology. Natick officials believe that the Army has sufficient research data, except for animal feeding studies, to support petitions to FDA for approving irradiated meats. Although some additional work remains to be done on several aspects of the technology, we believe that it is time for the Army to reevaluate the need for continuing Natick's research at the $3-million-a-year level. This reevaluation should consider that a minimum base would be needed until the program can be completed.

ECONOMIC BARRIERS

Irradiated meats offer some potential advantages for use in military rations, especially since no refrigeration will be needed during long periods of storage. It has been long recognized that a substantial commercial market, in addition to the military market, would be needed to attract private investment in this technology. Recent improvements in thermal processing technology and the Army's practice of providing soldiers with fresh or frozen meats whenever possible could, because of their high acceptability, limit the impact irradiated meats would have on military rations. These factors and the lack of a known commercial market for irradiated meats emphasize the uncertainties about whether this technology would be practicable from an economic standpoint.

The U.S. food industry has not commercially adopted irradiated foods that have been approved by FDA (low-dose irradiation of wheat, wheat products, and potatoes). Therefore, FDA approvals do not ensure that a commercial market for the irradiated foods will exist.

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We believe that the Army's program should be brought to a definite conclusion. The high-dose meat sterilization

technology has sufficient potential to merit some continued Government investment. The level of that investment, however, should be consistent with the uncertainties surrounding the program.

The Army has not yet been able to convince FDA that irradiated meats are safe and nutritious. Even with FDA approval, private industry may not be interested in using the technology. A prudent course for the Army would be to concentrate most of its research efforts on petitioning for and obtaining FDA approval of irradiated chicken. Based on that petition and FDA's actions, a determination could be made about (1) the potential for, and research that would be involved in, obtaining further FDA approvals, (2) the potential civilian and military market for irradiated meats (using irradiated chicken as a test), and (3) the cost to bring the program to a conclusion.

RECOMMENDATIONS

We recommend that the Secretary of Defense have the Secretary of the Army develop a plan to complete the food irradiation program. The plan should

--restrict animal feeding studies to those needed to obtain approval of irradiated chicken;

--evaluate the need for continuing food irradiation research by Natick at the $3-million-a-year level; and

--determine, using irradiated chicken as a test case, the desirability of further Government investment in high-dose sterilization of meats and the potential for successfully transferring the technology to industry.

AGENCY COMMENTS

We discussed our proposed report with Defense, Army, and Food and Drug Administration officials. Their comments and suggestions were considered in preparing the final report.

Army officials said they agreed with our recommendations and were planning to implement them. With respect to continuing the food irradiation program after a successful petition to FDA and a decision for continued Government interest, Army officials said that the present Army position is that some other Government agency should be responsible for establishing an irradiated food industry. They recognize that the Army would have a supporting role in the technology transfer process.

CHAPTER 8

SCOPE OF REVIEW

Our review was conducted primarily at the Army Natick Research and Development Command in Natick, Massachusetts, and the Headquarters Office, Army Medical Research and Development Command of the office of the Surgeon General in Washington, D.C.

We reviewed hearings on the status of and prospects for food irradiation technology held from 1955 to 1970 before the Joint Committee on Atomic Energy and records, documents, reports, and evaluations bearing on the food irradiation program and food irradiation technology in general.

We discussed food irradiation research matters with officials of the Department of Defense; the Department of the Army; Food and Drug Administration; Department of Agriculture; Federation of American Societies for Experimental Biology; Committee on Food Irradiation of the National Research Council; and Industrial Bio-Test Laboratories, a subsidiary of Nalco Chemical Company. We also solicited the views of six private food processors, three commercial radiation service firms, and others on the commercial prospects for, and their interests in, food irradiation.

We attended the International Symposium on Food Preservation through Irradiation in Wageningen, the Netherlands, and held discussions with officials of the International Project on Food Irradiation in Karlsruhe, Germany. Also, we discussed irradiation research with officials of the Federal Republic of Germany's Institute for Bio-chemistry and Food Technology (also located in Karlsruhe) and attended the annual meeting of the Interdepartmental Committee on Food Irradiation in Washington, D.C.

APPENDIX I

THOMAS J. DOWNEY
2ND DISTRICT, NEW YORK

328 CANNON HOUSE OFFICE BUILDING
TELEPHONE: (202) 225-3335

DISTRICT OFFICE:
4 UDALL ROAD
WEST ISLIP, NEW YORK 11795
TELEPHONE: (516) 661-6777

Congress of the United States
House of Representatives
Washington, D.C. 20515

August 5, 1977

COMMITTEE ON
ARMED SERVICES

SUBCOMMITTEES:
MILITARY PERSONNEL
MILITARY COMPENSATION

SELECT COMMITTEE ON AGING

COMMITTEE ON
SCIENCE AND TECHNOLOGY

SUBCOMMITTEES:
FOSSIL AND NUCLEAR ENERGY
SPACE SCIENCE AND APPLICATION

Elmer B. Staats
Comptroller General of the United States
General Accounting Office
441 G Street
Washington, DC 20548

Dear Mr. Staats:

The irradiation of food was first studied by the United States Army over 25 years ago. The theory behind this type of food treatment is that it would be able to sterilize food, ridding it of pests and mold, and prolonging its shelf life.

The Army conducts this research at Natick Laboratories in Natick, Massachusetts. Unfortunately, the approximately $50 million that the Army has spent in the study and treatment of irradiated food has only resulted in one food product which has been approved for human consumption by the Federal Drug Administration, and that approval has been recinded.

In fiscal year 1977 the Army will spend $6.4 million on food irradiation at Natick.

One of the problems with this program is that the cure is worse than the disease. That is to say that in the process of irradiating food the Army has made it virtually inedible.

One method of irradiating the food at Natick calls for the bombardment of potatoes and other food products by gamma and beta rays. It should be evident to the Army and its legion of researchers that most people prefer their potatoes with butter or sour cream!

In any case, I believe that this is a costly and ineffective program which continues to cost the taxpayer millions of dollars. I therefore request that the General Accounting Office begin an investigation into the cost-effectiveness of the Natick food irradiation program.

Attached for your information is a preliminary report prepared by my staff on the Natick facility.

Please contact Phil Sparks of my office on this matter.

Sincerely,

THOMAS J. DOWNEY
Member of Congress

TJD/ps:ct
Enclosure

APPENDIX II

MARGARET M. HECKLER
10TH DISTRICT, MASSACHUSETTS

VETERANS' AFFAIRS COMMITTEE
JOINT ECONOMIC COMMITTEE
AGRICULTURE COMMITTEE

Congress of the United States
House of Representatives
Washington, D.C. 20515

January 4, 1978

Honorable Elmer B. Staats
Comptroller General
441 G Street
Washington, D.C.

Dear Mr. Staats:

The General Accounting Office (GAO) has been requested by Congressman Thomas J. Downey to perform an audit of the Radiation Preservation of Food Program which has been conducted by the Department of the Army over a period of approximately twenty-five years.

Because of my deep and abiding interest in the problems of nutrition and the need to assure an adequate diet and food supply for the people of the United States and the world, I am interested in the potential of preserving food by the irradiation process as a means of contributing to the solution of the food problems of the world. As you no doubt are aware, this program began as part of the Atoms for Peace Program and has been directed and supported by Congress over the years.

Radiation preservation of food can result in significant reductions in energy costs compared to frozen and canned foods. In view of the ongoing energy problems, this aspect should be of great importance in the audit. The Department of Agriculture has given the meat processing industry until March 16, 1978, to submit data concerning the use of nitrates and nitrites in cured meat products because the use of these chemicals can result in the formation of carcinogenic nitrosamines in the products. The banning of cured meat products would have disastrous results on many small meat packers and processors as well as hog growers. Preserving meats by the radiation process could well be the salvation of this industry. This problem should receive careful attention. Similarly, it is conceivable that in the near future the Environmental Protection Agency might ban the use of chemicals for fumigating

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APPENDIX II

grains to control insect infestation. Low dose radiation of grains can accomplish this and prevent the loss of considerable supplies of grains.

While under the existing law (Food Additive Amendment of 1958), radiation is defined as a food additive, there is an ever-increasing body of scientific authority which is of the opinion that radiation of food should be considered a "food process" similar to "thermal processing," rather than a "food additive." I hope that the audit will consider a recommendation to Congress to this effect since this change would facilitate the commercialization of the food irradiation process.

I would appreciate it if you would see that the present audit addresses itself to these important points and please furnish my office a copy of the report when it is prepared. Thank you for your attention to this request.

Sincerely,

Margaret M. Heckler

MARGARET M. HECKLER
MEMBER OF CONGRESS

MMH:jrh

CHRONOLOGY OF ARMY FOOD IRRADIATION PROGRAM

1953 The Army started food irradiation program.

1954-59 Short-term animal feeding studies conducted using 54 irradiated foods.

1956-65 Long-term animal feeding studies conducted on generations of animals using 22 irradiated foods.

1958 Food Additives Amendment of 1958 passed, including food irradiation in the definition of food additives.

1959 The Army canceled its plans to construct a pilot irradiation food plant in Stockton, California.

1960 Responsibility for U.S. food irradiation program split, with the Army assuming responsibility for high-dose irradiation, and AEC, low-dose irradiation.

1962 The Army petitioned FDA for approval of irradiated bacon using cobalt 60 as a radiation source. The Army and others also petitioned for approval of irradiated bacon using other radiation sources. 1/

Private citizens petition FDA for approval of irradiated wheat and wheat products (cobalt 60 as a radiation source). 1/

1963 The Army and AEC petitioned FDA for approval of irradiated potatoes to prevent sprouting.

Private firm petitioned FDA for approval of irradiated wheat and wheat products using electron beam as radiation source. 1/

FDA approved Army petition for irradiated bacon (cobalt 60 source).

FDA approved petition for irradiated wheat and wheat products (cobalt 60 source).

FDA approved petition for irradiated bacon (electron beam source, 5 MeV.)

1964 AEC petitioned FDA for approval of irradiated wheat and wheat products using cesium 137 as a radiation source. 1/

FDA approved the Army-AEC petition for irradiated potatoes.

APPENDIX III

	FDA approved petition for irradiated wheat and wheat products (cesium 137 source).
	FDA approved petitions for irradiated bacon (cesium 137 and X-rays from electron beams, 5 MeV.).
1965	FDA approved petition for irradiated bacon using electron beam (10 MeV.).
1966	FDA approved petition for irradiated wheat and wheat products (electron beam source, 5 MeV.).
	The Army petitioned FDA for approval of irradiated ham.
1968	FDA rescinded approval of irradiated bacon; the Army withdrew its petition for approval of irradiated ham.
	The Army canceled its plans for a pilot plant meat irradiation facility.
1970	The Army considered terminating its food irradiation program. Congressional interest kept the Army in the program.
1971	The Army initiated a third phase of animal feeding studies (irradiated beef).
1975	The Army's animal feeding studies were expanded to include irradiated chicken and ham and pork.
1977	The Army declared its beef and ham-pork animal feeding contracts in default.

1/A major portion of data for these petitions was contributed by the Department of the Army.

SYNOPSIS OF QUESTIONS RAISED ABOUT WHOLESOMENESS AND TASTE OF IRRADIATED FOODS AND RESPONSES BY NATICK RESEARCH AND DEVELOPMENT COMMAND OFFICIALS

A number of research studies conducted by non-Army scientists during the 1960s and early 1970s have questioned the wholesomeness of irradiated foods, citing harmful chemical and biological effects, unfavorable sensory characteristics, and problems associated with animal feeding studies. Some research studies indicated that irradiation leads to considerable decreases in thiamine in pork roasts and in the amount of amino acids and vitamins A, D, and E in fish meal. Other research studies indicated that some radiation doses do not inactivate the spores of the bacteria clostridium botulinum and that they leave a disagreeable flavor in bacon and produce tumors in test animals.

NATICK RESPONSES

According to Natick officials, most of these studies are based on foods processed by technology which is now obsolete. No recent evidence of adverse wholesomeness findings have been reported. They stated that, after these studies were made, improvements in radiation technology had resolved some early problems with vitamin loss. Other studies alluding to reports that animals developed tumors were based on faulty experimental design.

All food processing methods, including radiation, reduce the amount of thiamine in food. However, according to Natick officials, the loss of thiamine is minimized by irradiating foods, such as pork roasts, in a frozen state. Irradiation, along with other food preservation methods, can lead to some destruction of nutrients. Natick officials said, however, that technology improvements, such as low temperature irradiation, minimize these losses. They said also that three recent reports on nutritional aspects showed irradiation to be no more deleterious to nutrients than other processing methods.

According to Natick officials, studies have shown that applying the established minimum required doses of irradiation kills off the most radiation resistant bacteria strains. Bacon irradiated using the technology developed at Natick has excellent flavor and high acceptability as evidenced by favorable results from military acceptance tests in the 1960s. Natick officials stated that conclusions, drawn from experiments in which irradiated fish, when fed to test animals, produced harmful effects on the animals' reproductive

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systems and in their offspring, were not valid because the tests were not properly designed.

Experiments in which wheat flour, irradiated at 5 million units of absorbed radiation, was fed to test animals and produced tumors are of questionable validity because the applied dose was 100 times the maximum dose approved by FDA.

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