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# REPORT OF THE AD HOC GROUP FOR IRRADIATED FOOD PROGRAM

Army Scientific Advisory Panel
Washington, D. C.

May 1975

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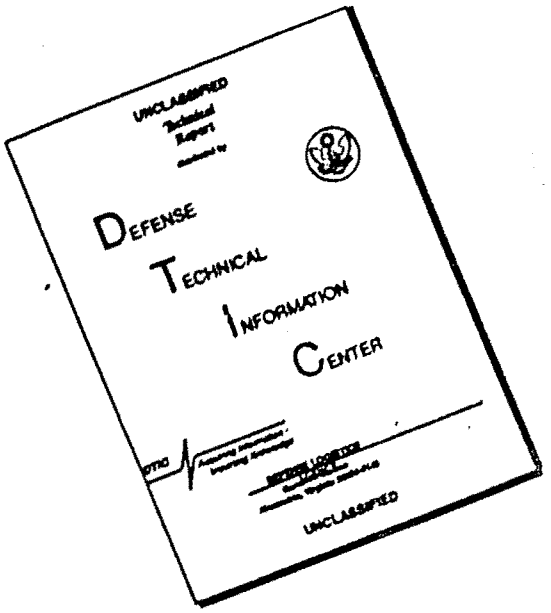


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# REPORT OF

# THE ARMY SCIENTIFIC ADVISORY PANEL

# AD HOC GROUP

# FOR

# Irradiated Food Program





MAY 1975

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Final Report
Army Scientific Advisory Panel
Ad Hoc Group on Irradiated Food

I. Background.

The background statement of the Ad Hoc group's Terms of Reference (Appendix A), indicates that the Secretary of the Army is anxious to insure that the Army Irradiated Food Program is soundly planned and progressing at the most expeditious but realistic pace possible to enable an early decision to be made on the level at which the program should be continued.

The Army Food Irradiation program dates back to 1953, when it was originated as part of the "Atoms for Peace Program". (Appendix B) Through the years, the program has been refined and reoriented from a total foods-total dose range effort to the current effort of proving the wholesomeness of meat items treated with high doses (Mrad range) of irradiation. In 1970, the Army was committed to Congress to carry out wholesomeness tests on four meat items, starting with beef. This commitment required that the test be continued until the products were approved or disapproved by the Food and Drug Administration (Appendix C).

Currently the Army is entering into the last year of its beef wholesomeness testing contract and a decision has recently been made to start up the three additional meat items testing programs.

The group was asked to consider the questions: (a) Assuming that all required approvals have been obtained, how significant will the existence of irradiated foods be to (1) the Army, and (2) the world as a whole; (b) What actions should be taken, if any, to expedite the approval process"?

II. Study Approach:

The Group (Appendix D) began its deliberations by reviewing the Terms of Reference and outlining the areas necessary to be covered, both in program background and ongoing related efforts, in order to respond to the questions posed to the Group.

The Group held two one-day meetings at the Pentagon to hear from designated briefers from the several agencies determined to be most directly involved with the irradiated food program. Due to the suspense date provided for completion of the final report, the Group could not make any site visits (i.e., Natick Development Center or Industrial Bio-Test Corporation). However, based upon the material that was made available and the quality and depth of briefings that were presented, the Group concluded that it could make a meaningful response in the time frame allotted to the questions addressed to it.

During the first meeting, the Group was given an understanding of the rules and regulations governing wholesomeness testing by a representative from the Food and Drug Administration. In addition, the background of the entire food irradiation program, from conception to current status was provided by a Natick Development Center's representative. The history of the wholesomeness testing program of beef, to date, was provided by a Army Medical R&D Command representative. (Memorandum For Record at Appendix E.)

At the second meeting, the Group heard from several briefers outside of the DOD. International irradiated food programs and the implications of the U.S. efforts were discussed by representatives from the Department of State. A review of the Army's program was provided from the viewpoint of the National Research Council's Committee advisory to the Natick Development

Center on food irradiation, by that committee's chairman, who also informed the Group of several of the implications that this program held for the American Food Industry. The Group also heard from a representative of the National Science Foundation, who discussed how a technology assessment might contribute to an understanding of the implications of introducing food irradiation technology. The last briefer of this session was from the Energy Research and Development Administration, who monitors the "remnants" of the Atomic Energy Commissions low-dose irradiation program (Memoranduum For Record at Appendix F).

In addition to inputs from these meetings, the Group reviewed a large volume of literature on the subject, provided by numerous sources, including the Departments of the Army, Commerce, Agriculture, and State; the Energy Research and Development Administration; the National Science Foundation; the International Congress of Radiation Research; the Interdepartmental Committee for Radiation Preservation of Foods; and the Congressional hearings before several joint/house committees of the Congress of the United States. The following report is based on this input.

III. Administrative Summary:

A. Use of irradiated foods would improve logistics and morale in the US Armed Forces and in those of its allies.

The Army should continue with the wholesomeness testing program of the "big four" meat items (beef, pork, chicken, and ham).

B. Results of the beef tests, to date, are favorable.

Wholesomeness tests for irradiated chicken, pork and ham should start as soon as possible.

C. FDA approval of beef may permit a reduced protocol for testing the other meats.

Contracts for animal studies or the other meats should permit a reduction in number of animals to be used if agreed to be competent specialists and FDA officials.

D. Proof of wholesomeness is governed by law and regulation.

Continued quarterly conferences between FDA and Army representatives is an excellent method for accelerating up the approval process.

E. Annotated bibliographies of wholesomeness studies are essential to workers in the field and required by FDA.

The Army should fund for and have an updated bibliography prepared.

F. Preparation of petitions to FDA will require large amounts of and much repretition of data.

An information system should be funded and established to keep track of data to be used in the preparation of petitions.

G. A joint US-NATO military study on the impact of irradiated foods would be beneficial.

The United States should take the lead for such a study.

H. World usage of irradiated foods depends upon factors other than clearances.

A technology assessment should be conducted by a group outside of DOD, such as OTA, NAS/NRC or NSF.

I. World acceptance of irradiated food will be determined by influences external to the Army.

The Army should support only that part of the program relating to its needs. Promotional activity to the rest of the world should be done by other agencies with the Army providing data generated through its studies and its expertise and assisting in technology transfer.

IV. Introduction:

Before responding to the questions asked of this Group, it is important to comment upon the overall irradiated food program, specifically as it has developed within the Department of the Army. The committee believes that after a generally well supported beginning, the irradiated food program ran into considerable difficulties during the late 1960's, apparently because of the lack of interest in the Army and DOD. It probably would have lapsed had there not been Congressional intervention in 1969-70. The program, since 1970, has been continued at a prescribed level within the Army. The recent interest shown by the Secretary of the Army may well provide the emphasis needed to insure the program's successful conclusion. The Group recognizes that the extended periods of time required for the conduct of the extensive animal tests needed to prove wholesomeness make this program more difficult to support than others which take less time. It should be noted however, that the time does not exceed that for fielding some of the new weapon systems. The Group does believe that support to the irradiated food program will prove to be of significant value to the Army.

As will be brought up later, the Group believes that the technology to effectively and beneficially irradiate food is now available. At the same time, the Group believes that the major problem to be overcome lies in the acceptance phase. It questions, however, whether the Department of the Army is really the proper U.S. government agency to be involved with the promotion of the general acceptance of this process. Since the Army is committed to the four meat wholesomeness testing programs, these, the Group believes, should be continued under Army sponsorship. The Group is of the unanimous opinion, however, that responsibility

for the wholesomeness testing of other items, for getting American industry involved, and most importantly, for getting the process "sold" to the American public belongs elsewhere in the federal Government (i.e., Commerce, USDA, Interdepartmental Committee, and for international applications, Department of State). The Group recognizes the importance of Army involvement with the transfer of irradiation technology to industry at the successful conclusion of the Army's wholesomeness program.

V. Assuming that all required approvals have been obtained, how significant will the existence of irradiated foods be to:

a. The Army? - The significant impacts, which food that has been sterilized by the irradiation process could have upon the Army, are primarily in the areas of logistics and morale. There would also be potential health benefits to be derived from the use of this process.

(1) Logistics: In a study conducted for the Department of Army by the Department of Commerce (Footnote A) it was shown that had the U.S. Troops in South Vietnam in FY 1968 been provided with irradiated canned-chilled ham, six-way frozen beef, frozen chicken, pork and bacon, the U.S. government would have realized approximately $18 million in savings during that fiscal year. This savings estimate did not consider the time and manpower savings that would result during preparation of these products already at room temperature. The burdens that refrigeration impose upon the logistics system in order to serve fresh/frozen components of the A-ration are well recognized; they need not be further documented here. The fact that the irradiation process produces very acceptable products, which are shelf-stable without refrigeration, would permit the logistical

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A. Cost-Benefit Analysis, Potential Radiation Sterilized Military Subsistence Items, Department of Commerce, Washington, DC, 1972, page 3.

distribution system to handle such products in a manner similar to that employed in storing/distributing non-perishable items. The advantages irradiated foods offer in meeting the necessity for pre-stocking rations in the event of mobilization are also clearly evident.

(2) Morale: The fact that irradiated products are shelf-stable without refrigeration makes it possible to provide and to introduce these foods to troops subsisting in the field at earlier stages of a conflict then is now possible. In addition, since the sterilization process is a "cold" process, such packaged irradiated products are more acceptable than currently used canned products that have been thermally processed to achieve sterilization. This process can be applied to a wider range of products than is now available, and could reduce the monotony of current rations. The availability of irradiated products should also prevent the disparity of feeding levels, as occurred in South Vietnam, where one element of the U.S. Forces, with refrigeration ate normal A-rations, while another element, without refrigeration, had to exist for an extended period of time on operational and B-type rations.

(3) Health: Although there currently is no signficant problem in the Services with food-borne diseases, such as salmonellae or trichinosis, the fact that such diseases do exist must be considered. The presence of the military veterinary inspection service contributes to the low disease incidence in the Services. But the important factor to be recognized is that irradiation sterilization can achieve more successful sterilization of packaged products than can be achieved by conventional methods, and it does so at much lower temperatures. As a consequence, a whole turkey or 20 pound ham, for example, can be successfully sterilized, whereas to process

the same items thermally would cause over cooking of the outer portions, before the internal temperatures reached levels lethal to organisms that might be present.

(4) NATO: The Group believes that the successful acceptance of irradiated food items would prove beneficial to military allies of the U.S., and particularly to the NATO countries because of the similarity of diets amongst them. The benefits that are gained by U.S. Forces would also accrue to our allies.

The Group believes a joint military study, of the use of irradiated food by representatives of the U.S. Forces and its allies, such as NATO, would be useful.

(5) Other Factors: In the review of materials and based upon several of the briefer's comments, the Group became aware of a situation that is of grave importance to the overall success of the irradiated food program for the Army. The concern is that there are factors, beyond the Army's proof of wholesomeness of these various food items, that will equally influence the program's eventual success, such as the industrial adoption of the irradiation process; the public acceptance of irradiated food products; and the development of additional, approved irradiated food items. Failure to solve these and other relevant problems may well lead to failure of the total food irradiation program, despite ultimate successful proof by the Army of wholesomeness of the four meat items under test. This is discussed further in the second part of this question.

b. The world as a whole? - The significance and scope of this portion of the Group's task is believed to be of far greater magnitude then could

be properly addressed in the time allowed for the Group's study. The Group, therefore, believes that this question deserves attention by the process of a properly conducted technology assessment. Such an assessment, performed under the auspices of an agency such as the National Science Foundation or the Office of Technology Assessment, and under the sponsorship of a federal agency (other than DOD) would help to identify the impact of introducing food irradiation technology on the nation's and world's food supply. The Group makes this suggestion because of the benefits to be gained from both low and high dose irradiation in meeting the world's food supply problems.

The Food and Agriculture Organization and the International Atomic Energy Agency joint panel meeting (18-22 November 1972 - Bombay, India) discussed various aspects of concern in the introduction of irradiated foods into developing countries.(a) In summarizing the proceedings of this meeting, the conferees address several pertinent factors that apply to the world food supply problem.

"Preventing food losses by the application of preservation technology is a major factor in helping to solve the world food problem. With proper use of food technology the quantity of food produced today would be more than enough to feed the existing population of the earth. Thus, any process that offers a way of saving even a small percentage of the food wasted merits attention in a hungry world."(b)

"Climatic conditions in these regions (developing countries) are characterized by high average temperatures and excessive humidity, both of which are conducive to food spoilage through microbial or insect action, as well as by physiological changes in food tissues.

It has been reported, e.g., that losses in cereals and leguminous seeds in 9 Latin American countries .... amounted to some 4.5 million tons of produce every year (14 to 50% of the total produce of the countries

concerned). Losses in yams in West Africa are around 1 million tons annually. In Niger, 1.1-1.4 million tons, i.e., 45-60% of the total annual crop of millet, sorghum, and kidney beans are lost regualrly. In India, losses in potatoes and onions are usually around 25% of the total annual crop (5 and 1.5 million tons, respectively). The loss in grain is around 15%."(c) These losses can be reduced by low dose irradiation, which is a program of the Energy Research and Development Agency.

"In many developing countries fish protein, available from the sea, cannot reach in-land areas for the lack of efficient preservation methods, thus depriving a protein-starved population of high-value protein."(d)

"It is believed that food irradiation could render very valuable service against most of the problems mentioned above."(e)

"Thus, in many developing countries it would appear to be more economical to introduce food irradiation than any of the other food preservation processes."(f)

Although none of the above quotations can be challenged on the basis of facts currently known regarding the benefits of high and low level irradiation of foodstuffs, it should be pointed out, in balance, that the validity of each of these statements depends upon a number of other factors. In particular, appropriate storage facilities for food products following irradiation that would protect the treated foods from further damage by reinfestation with insects or molds would be necessary to realize the potential benefits of irradiation treatment. Further, an adequate transportation and distribution system would also have to be available to bring the products to the irradiation facilities and redistribute the products to the area where they would be consumed if the stated benefits were to be realized. The FAO/

IAEA report recognized the need for these elements of "infrastructure" in some countries in the referenced report, as will be seen in the following quotation.

"The insufficiencies of the infrastructure in some developing countries no doubt work as delaying factors against the introduction not only of traditional food processing techniques but also of irradiation.

Centralized handling of the product to be treated is a precondition of economical irradiation. Where growing areas are not concentrated transportation problems may emerge .... In the case of grain irradiation, the availability of roads and silos is extremely important...

In many countries the present lack of suitable and inexpensive packaging materials is a definite handicap for practical food irradiation..."(g)

"It was recognized that in most developing countries too little is known about the economic importance of food irradiation in quantitative terms... This situation should be corrected through adequate survey."(h)

The Group recognizes that the above referenced panel proceedings were conducted by advocates of irradiated foods. Although their comments were biased favorably towards such foods, they did highlight some of the same problems noted by this Group, and they also concluded "economic studies"

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a. Aspects of the Introduction of Food Irradiation in Developing Countries, proceedings of a panel, Bombay, 18-22 November 1972, organized by the FAO/IAEA, International Atomic Energy Agency, Vienna 1973.
b. Ibid, Page 97.
c. Ibid, Page 97-98.
d. Ibid, Page 98.
e. Ibid, Page 98.
f. Ibid, Page 99.
g. Ibid, Page 100.
h. Ibid, Page 100-101.

were lacking in the developing countries. It is probable that had they considered the problems related to introduction of irradiated foods in "developed" countries, they would find "economic studies" were still needed.

In part, supporting the preceeding comment, the Group noted with interest the fact that, in spite of the apparent need for the irradiated process, there are currently 17 products approved for use in 16 countries of the world, and yet there is little or no production of any of these irradiated foods. In particular, Russia exemplifies a fairly well developed country in which an irradiated food program was initially begun with apparent enthusiasm. As reported by the Department of State briefer, Russian enthusiasm has dwindled to the point that the program currently receives little emphasis in that country. These observations further support the Group's belief that for the irradiated process become a success for there are other fundamental factors to be addressed besides proof of wholesomeness.

VI. What actions should be taken, if any, to expedite the approval process?

In order to address this question the Group solicited and heard comments from practically every briefer; exhaustively reviewed the FDA regulations; reviewed the existing Army protocol for testing wholesomeness of irradiated beef; and also reviewed literature concerning the regulatory responsibilities of the FDA.

Based upon these efforts, the Group concluded that the FDA could not and should not be "directly" pressured to shorten or reduce the wholesomeness test requirements. Further, it is the responsibility of the petitioner (Army) to prove the wholesomeness of irradiated food products as required by the Food, Drug and Cosmetic Act and pertinent FDA and USDA regulations.

Having said this, the Group did conclude, however, that the ongoing study of wholesomeness of irradiated beef and its protocol for testing were set up with extreme care to answer any plausible foreseeable problems.

A summary review of the results of animal studies on irradiated beef, indicates that no radiation related pathological problems have developed to date. Thus, it appears appropriate to initiate the concurrent studies of the three additional meat items. (Chicken, pork, and ham.)

If these studies are initiated before completion of the study of irradiated beef, it is desirable to follow the protocol utilized in the beef study insofar as practicable. That study involves rather large numbers of animals (approximately 1,500 dogs, 27,000 rats and 20,000 mice per food item tested). However, on the assumption that the irradiated beef petition is approved by FDA, it is possible that the ongoing tests of chicken, pork and ham might be simplified by reduction of the total numbers of animals involved in the testing program. Such changes in protocol should receive the indorsement of competent toxicology and statistical consultants and be concurred in by FDA before they are implemented.

A further complication of the large numbers of animals to be utilized in the proposed concurrent testing of chicken, pork, and ham is that of attaining and (more importantly) housing the animals needed, as required by the test protocols. Available toxicology laboratory facilities are already rather heavily taxed by studies being supported by the Environmental Protection Agency (EPA) and the National Institutes of Health (NIH). Under these circumstances, it may not be possible to undertake the three additional protocols concurrently without providing for the construction of new kennel and animal room facilities for prospective contractors.

Lastly, the task of monitoring the ongoing studies and of the preparation of the respective petitions to FDA for approval of the

irradiated food products must not be underestimated. Frequent on-site visits to the contractor's facilities, review and forwarding of contractors reports to FDA and joint conferences with FDA will be required for the duration of the animal studies. These activities will require in the order of several man-years of professional time annually.

The end result of these efforts will be four petitions for submission to the FDA, each one of which will represent the total collection of data available for a particular family of foods. Although some economy of paperwork will result from the use of cross references or "masterfiles", the anticipated size of each petition is approximately 20 linear feet of bound 8 x 10 1/2" formal reports. This volume of typed material is most efficiently handled by magnetic word-processing equipment, such as the IBM MTST or the Olivetti S-14 magnetic tape typewriters. Plans for preparation of the eventual petition should include appropriate utilization of word processing techniques and equipment.

VII. Conclusions and Recommendations:

A. Conclusion: That the adoption of irradiated foods could significantly impact upon the Department of the Army, primarily in the areas of logistics and morale. A similar impact should pertain to the military forces of alliances formed by the U.S. Government, particularly, with NATO. (Page 6)

Recommendation: That the Army continue the wholesomeness testing program for the "big four" meat items. (Beef, chicken, pork, and ham).

B. Conclusion: That the results of the beef tests, to date, warrant the initiation of tests for the three additional meat items. (Page 13)

Recommendation: That the wholesomeness tests for the three additional meat items (chicken, pork, and ham) be initiated as soon as possible.

C. Conclusion: That, although there is insufficient evidence yet available from the beef wholesomeness tests to warrent modifications of the protocols to be used for the chicken, pork and ham tests, there is promise that as the beef studies progress, evidence will be developed to justify a modification of these protocols. (Page 13)

Recommendation: That the contract for the tests to be used to establish the wholesomeness of chicken, pork and ham provide for a changing of the protocols to permit a reduction in the number of animals used in the feeding programs, if such changes are agreed to by competent toxicologists, statisticians, and FDA officials.

D. Conclusion: The requirements for proof of the wholesomeness of irradiated foods are defined by the Food, Drug and Cosmetic Act and pertinent regulations. Therefore, short of a changing of the applicable laws, there is no method of speeding up the approval process for irradiated beef, other than by continuing the present exchange of data between the Army and the FDA. (Page 12)

Recommendation: Since the quarterly conferences between the FDA and Army representatives promised to provide a positive means of achieving the earliest possible approval of irradiated meat products, they should be continued.

E. Conclusion: That an annotated bibliography on wholesomeness of irradiated food, similar to the one prepared in 1966 by Reber, would be most beneficial to personnel working the program. (Page 14)

Recommendation: That the Army fund and have the suggested bibliography prepared.

F. Conclusion: Since the preparation of the petitions to be submitted to FDA will require sholesomeness data, technological information, and bibliographic references, much of which is repetitive, an information system would shorten the preparation time considerably. (Page 14)

Recommendation: That an irradiated food information system be established and funded to keep track of this information, prepare bibliographies, and help in the final preparation of the petitions.

G. Conclusion: A joint military study that addresses the impact of irradiated foods upon the Army and NATO nations might prove to be beneficial. (Page 8)

Recommendation: That a joint military study be conducted by the U.S. and allied nations, such as NATO nations, to determine the impact of irradiated foods upon the military operations of those nations. The conduct of such a study could be tasked to the United States.

H. Conclusion: If the objective of the U.S. food irradiation program is to commercialize food irradiation and promote the use of irradiated food throughout this country and the world, it is necessary to consider what steps need to be taken beyond the submission of petitions to FDA. Successful clearances on four meat items will not, by itself, result in the utilization of this technology. Beyond the wholesomeness questions upon which FDA will decide, there are economic, social, and institutional constraints which need to be addressed. Therefore, in order to provide a more adequate response to the second half of this Group's first question, a technology assessment, addressing the impact of irradiated foods upon the nation's and the world's food supply is needed. (Page 9)

Recommendation: That a TA be conducted under the auspices of a group such as OTA, NAS/NRC or NSF.

I. Conclusion: Although the Army's irradiated food program may have great significance for the world population, it appears that other factors will determine whether, and to what extent, irradiated foods will be adopted. Since these influences are external to the Army, it is questionable whether the Department of the Army should become involved with the promotion of the general acceptance of the food irradiation process beyond transfer and exchange of technical information. (Page 5)

Recommendation: That the Army continue to support that portion of the irradiated food program which relates to improving its logistical and flexibility benefits. The promotional involvement of industry and the "selling" of the process to the public should be handled by a federal agency other than the DOD, for which the Army should be prepared to provide data generated through its studies, its expertise and assist in technology transfer.

## LIST OF APPENDICES

| APPENDIX | | |
|---|---|---|
| A | - | Terms of Reference |
| B | - | Radiation Preservation of Food Program, US Army Natick Development Center Pamphlet, Natick, Massachusetts January 1975. |
| C | - | Secretary of the Army Letter to Congressman Price. |
| D | - | Membership List of Ad Hoc Group. |
| E | - | MFR of First Meeting. |
| F | - | MFR of Second Meeting. |

# APPENDIX A

TERMS OF REFERENCE
ASAP AD HOC WORKING GROUP
on the

Irradiated Food Program

5 February 1975

1. Background:

The Secretary of the Army is anxious to ensure that the Army Irradiated Food Program is soundly planned and progressing at the most expeditious but realistic pace to enable an early decision on the level at which the program should be continued. He has requested that an ASAP Ad Hoc Group be initiated at the earliest time to answer the following questions on the program.

2. Terms of Reference:

a. Assuming that all required approvals have been obtained, how significant will the existence of irradiated foods be to (1) the Army, and (2) the world as a whole?

b. What actions should be taken, if any, to expedite the approval process?

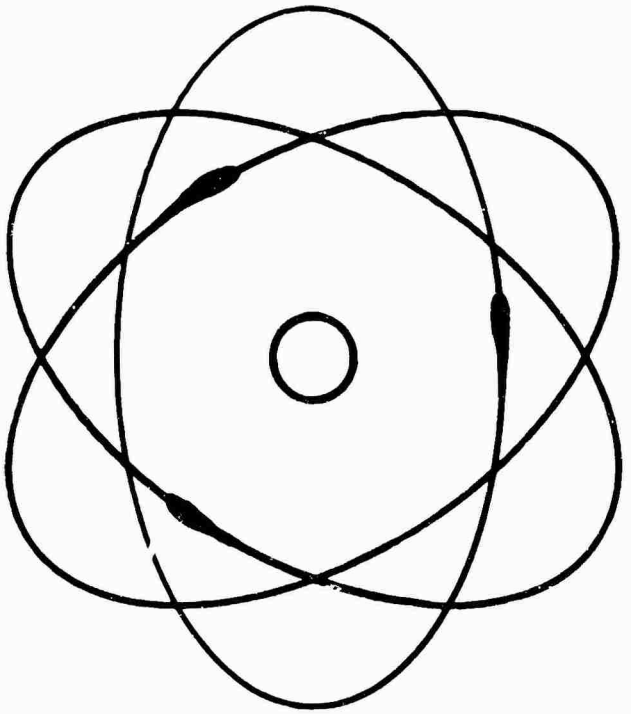
3. Termination:

The Chairman of the Ad Hoc Group is requested to conclude his efforts at the earliest possible date. However, a final report should be submitted not later than 28 March 1975.

## APPENDIX B

THE UNITED STATES ARMY'S

# RADIATION PRESERVATION OF FOOD PROGRAM



January 1975

RADIATION PRESERVATION OF FOOD DIVISION
FOOD ENGINEERING LABORATORY

UNITED STATES ARMY NATICK LABORATORIES
NATICK, MASSACHUSETTS 01760

# THE UNITED STATES ARMY'S

# RADIATION PRESERVATION OF FOOD PROGRAM

## *INTRODUCTION*

The National Food Irradiation Program is administered by two main federal agencies: the Atomic Energy Commission (AEC), and the Department of the Army (DA).

The AEC's program has the mission to foster low-dose (submegarad) application of irradiation processing to fruits, vegetables, fin fish, shellfish, poultry, and meats in order to retard their deterioration and extend their distribution time and shelf-life. Petitions have been or are being submitted to the Food and Drug Administration (FDA) for clearances on strawberries, irradiated to retard mold formation, and on papayas, irradiated to eliminate infesting insects.

The Army's Food Irradiation Program has the mission to develop the technology for using higher doses (megarad) to radiation-sterilize (radappertize) prepacked, enzyme-inactivated meat, poultry, and marine products. Radappertization results in a highly acceptable commodity, one that is familiar in appearance yet completely stable while stored at room temperature. This part of the DA effort has been pioneered by the Army Materiel Command's Natick Laboratories (NLABS). The Army's responsibility for establishing the safety and wholesomeness of radappertized foods is assumed by The Surgeon General's Medical Research and Development Command (MRDC).

Because the DA's high-dose program for making available shelf-stable, high quality, animal protein foods has broad implications for the nutritional, environmental, and economic well-being of our society as a whole, the Secretary of the Army, in 1970, specified that the Army's effort should encompass civilian as well as military considerations.

## *OBJECTIVES OF THE FOOD IRRADIATION PROCESS*

Five objectives can be achieved by applying ionizing radiation to foods:

a. total elimination of food-spoilage and/or disease-causing bacteria (radappertization) -- thus making prepackaged, enzyme-inactivated food stable for some years without the need for refrigerated storage;

b. sufficient reduction of spoilage organisms to retard spoilage (radurization) -- thus extending refrigerated shelf-life;

c. inactivation of bacteria posing public health hazards (radicidation) -- thus decreasing food poisoning potential of foods and destroying parasites transmitted through foods;

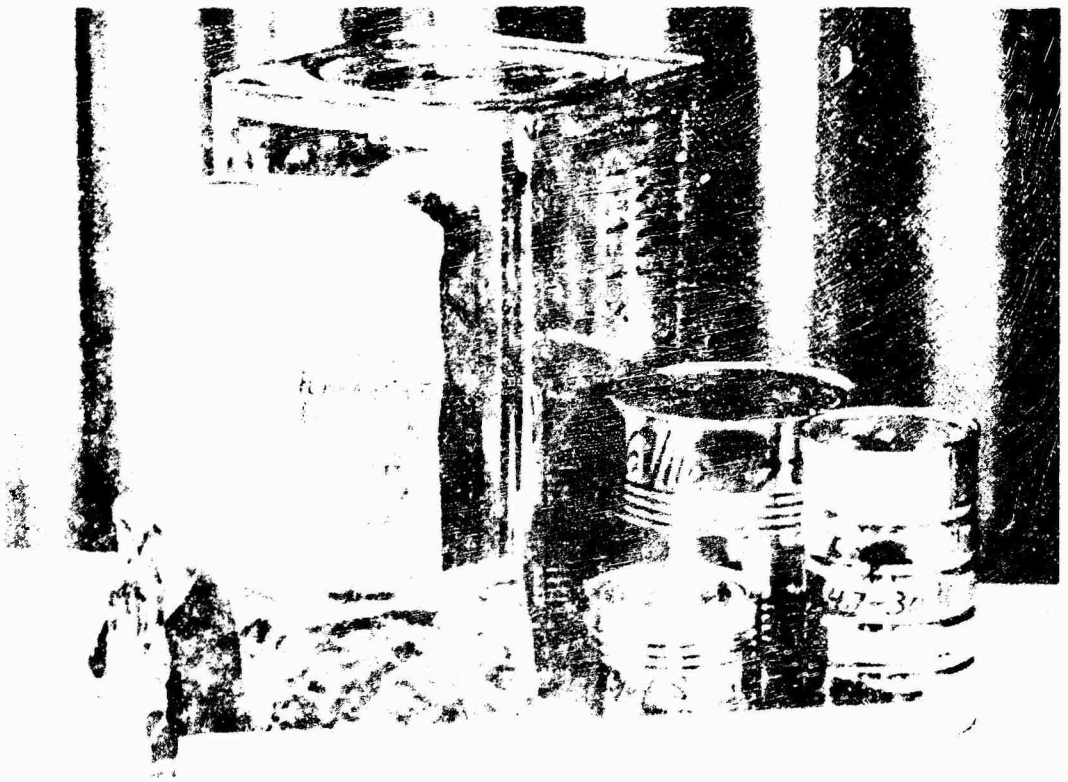
d. destruction of the eggs as well as other stages of insects infesting stored cereals and their products, grains, and fruits (disinfestation) -- thus preventing loss of the products during storage, provided such products are stored in containers that prevent reinfestation;

e. control of physiological processes to delay post-harvest ripening of fruits and to inhibit sprouting in tubers (potatoes) and bulbs (onions) (delayed maturation) -- thus extending their storage life.

*The irradiated potatoes and onions (left) have a longer useful storage life due to sprout inhibition by irradiation with 0.005 to 0.015 megarads.*

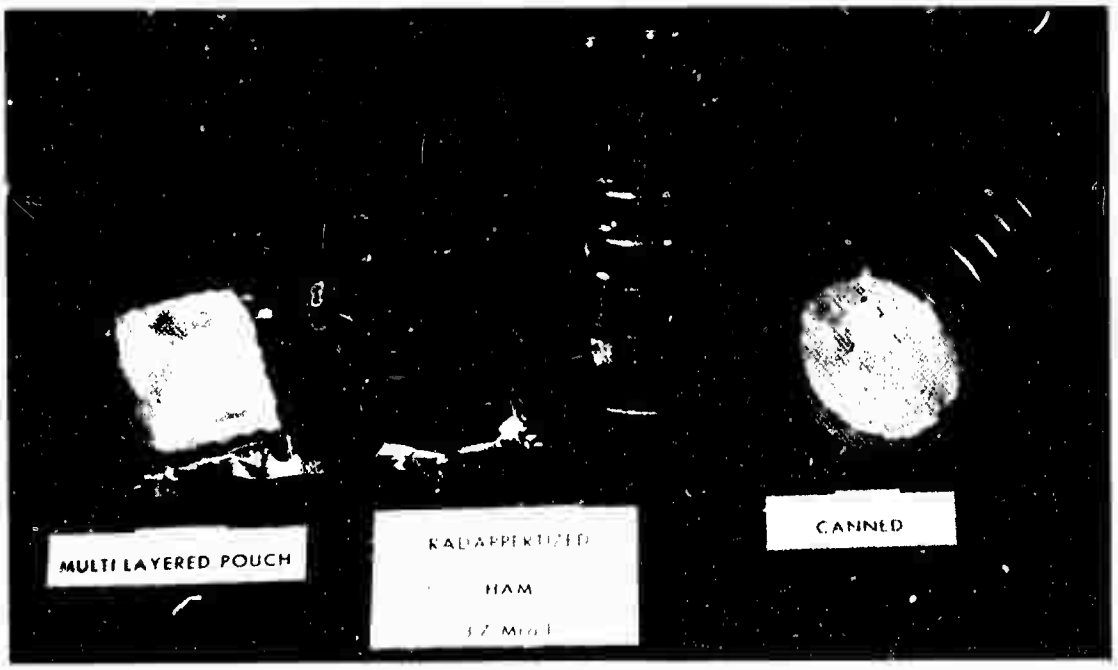
## ADVANTAGES OF FOOD IRRADIATION

Irradiation processing, particularly with high doses, has several food technological and economic advantages. Since it is a "cold" process, the nutritional quality and the general appearance, taste, texture, color, and flavor characteristics are only slightly affected. As a consequence, radappertized foods are highly acceptable to the consumer. Because the process can be applied to a wide variety of foods in many kinds and sizes of packaging containers, it has a versatility and flexibility far beyond the other preservation methods now used by the food industry.

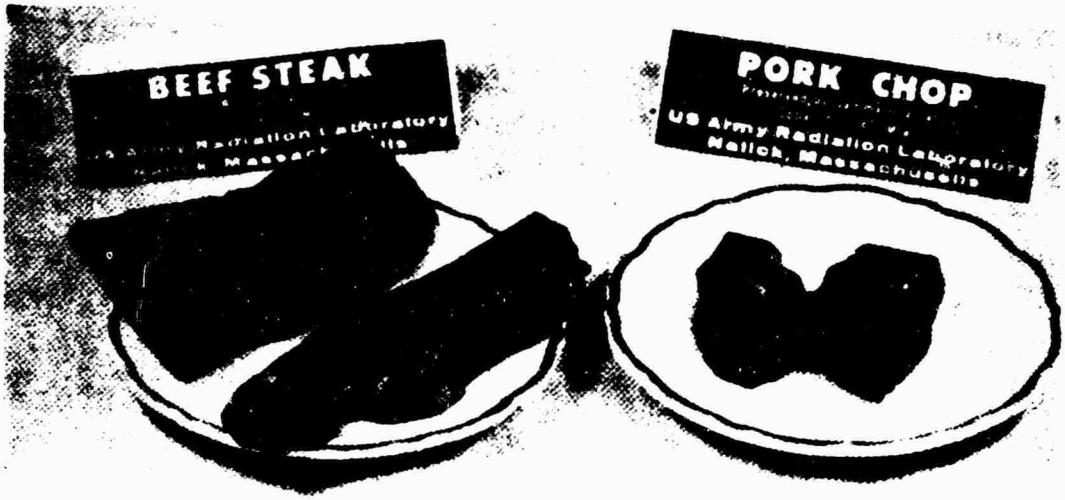


*Ionizing radiation's versatility makes it possible to use many different sizes and shapes of packaging containers.*

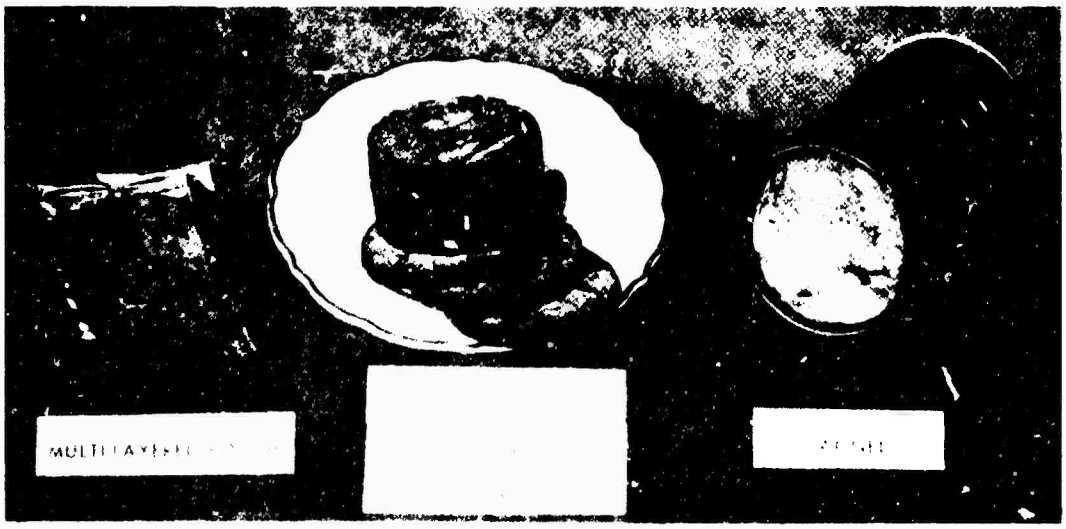
Furthermore, the radappertization process imparts long-term stability to nutritionally important and highly desirable foods. These foods are, therefore, ideally suited for situations in which resupply is difficult and/or refrigerated storage is limited, such as in disaster situations, civil preparedness activities, forward combat areas, submarines, and in inner/outer space. The overall advantages of having foods so processed will be improved performance and morale of personnel as well as savings on energy requirements, logistics, and food supplies.




*Radappertized, shelf-stable meats, such as the ham shown here, can be "dry" packed in large metal cans or in flexible pouches.*




Radappertized charbroiled beef steaks and pork chops are but two examples of many shelf-stable items for which there are no commercially available counterparts.



Because radappertized products receive a "precook" for enzyme inactivation, they may be eaten right out of their container or heated and used in your favorite recipe.

Because of enormous food spoilage losses in many areas of the world, there is little incentive to raise livestock and poultry to help meet the daily animal-protein needs of nonfarm populations. Fish protein, available from the sea, cannot reach inland areas for lack of efficient preservation methods. Thus, a large population is deprived of high-value protein.

It has been reported that the quantity of food produced in the world today would be more than sufficient to feed the existing world population if spoilage losses were greatly reduced or eliminated. Spoilage losses occurring during handling, transport, and storage represent not only loss of product but also, just as importantly, loss in soil fertility, manual labor, and monetary investment. Thus, very substantial nutritional and economic gains are possible by preventing losses currently suffered during the distribution and storage of food.

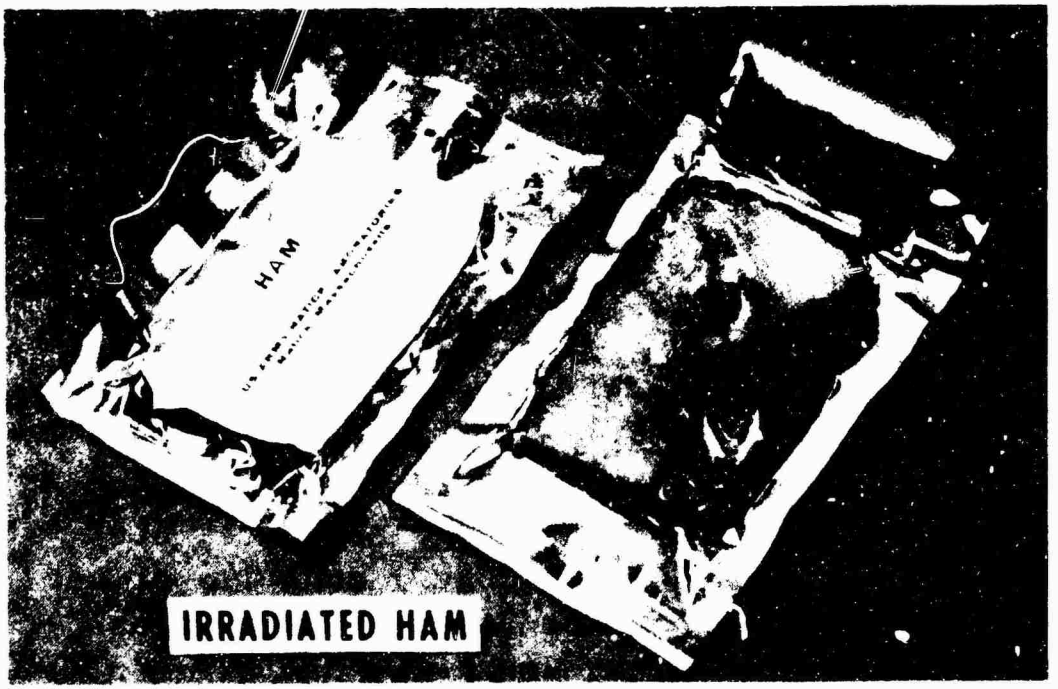
Exploiting irradiation preservation technology to achieve the objectives mentioned could be a major factor in helping solve the world food problem.

Prevention of diseases of public health importance can also be effectively accomplished by irradiating foods. Low-dose processing of foods destroys food-poisoning bacteria -- such as salmonellae, and parasites -- such as the beef and pork tapeworms, trichinae, and liver flukes; in addition, high-dose processing eliminates the threat of botulism in packaged foods.

Radiation processing can also decrease the dependence on chemical food additives currently used for

3. *Obtaining FDA approval of flexible packages used in irradiation processing with high energy electrons or gamma rays.* Specially designed flexible pouches -- made from a complex laminate of aluminum foil and polymeric materials -- are safe to use as food contactants during irradiation. These pouches are commercially available.

4. *Assisting the NASA Space Program by providing selected radappertized products.* Irradiated foods have been used on the APOLLO-17 moon flight and the recent SKYLAB mission. It is anticipated that radappertized, charbroiled beef steaks, ham, corned beef, and smoked turkey slices will be used on the upcoming joint United States-Soviet APOLLO-SOYUZ Test Program.




*"Juicy, chewy [irradiated] ham (shown here) and cheese on [irradiated] rye was one of the space culinary delights enjoyed by the APPOLLO 17 astronauts", one NASA official is quoted as saying.*

## LEGAL REQUIREMENTS

Despite these developments and numerous advantages, ionizing radiation cannot be used commercially in treating food until the food is approved in this country by the FDA. This approval is required because ionizing radiation legally is a "food additive" as defined by statute here (the 1958 Food Additive Amendment to the Food, Drug, and Cosmetic Act) and in several countries abroad.

## STATUS

Currently, the DA effort is directed towards obtaining clearance for radappertized beef. This involves a long-term animal feeding study and the acquisition of supporting auxiliary data. Design of the feeding study to test the wholesomeness of the beef was coordinated with the FDA and internationally recognized experts on nutrition and toxicology.

Under contract to MRDC, a private laboratory is conducting the long-term, multigeneration animal feeding study which involves a large number of dogs, rats, and mice per diet group, encompasses 25 different diet groups (including separate diets of electron and gamma-ray radappertized beef, heat-sterilized beef, and frozen beef) and will extend 3 years for dogs and up to 2 years for various generations of rodents. Among the health-associated parameters being examined to test for any toxic and/or carcinogenic (cancer causing) potential are: food consumption and feed efficiency, growth rate, longevity, reproduction, hematology, urology, and pathology.

Nearing completion, the dog portion of these experiments gives every indication of proving entirely satisfactory. It is too early, however, to evaluate the rodent portion; no adverse indications, however, have been noted to date.

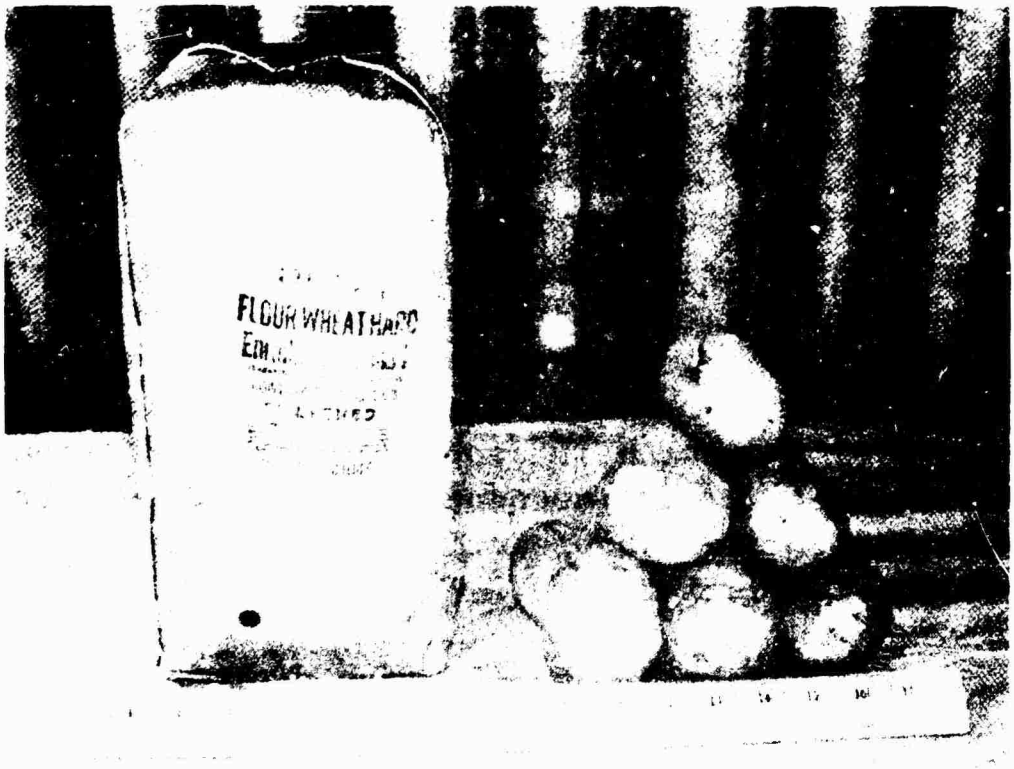
Among the auxiliary studies, specific tests with laboratory animals for any teratogenic (birth-defect) potential have been completed, and, although all the data have not been completely analyzed, preliminary indications are that the radappertized beef does not contain any birth-defect producing compounds. Tests for mutagenic (mutation producing) aspects are currently being designed.

Moreover, the volatile compounds found or formed in the radappertized beef have been separated and identified by NLABS' researchers. No compound has been isolated from irradiated beef that is not found in nonirradiated beef or as a naturally occurring constituent of other nonirradiated food products.

These studies are still in progress, and completion of the experiments and analyses of the data are anticipated for December 1976. The data will then be used to support a petition on irradiated beef to FDA.

## OUTLOOK FOR THE FUTURE

The immediate use of ionizing radiation is bound by the legal restriction in some countries that ionizing radiation is defined as a food additive (like chemicals) rather than as a physical method for food processing (such as heat). However, health authorities in sixteen countries have already approved at least one of seventeen irradiated foods for unrestricted consumption.




*Within the United States, approval has been obtained for irradiation of wheat and wheat flour for purposes of insect disinfestation and irradiation of potatoes for sprout inhibition.*

Since the United States has assumed a leadership role in developing this food irradiation process, the decisions regarding the wholesomeness of irradiated beef will have a significant impact on the world-wide adoption of the use of irradiation as a method of food preservation. These decisions will be based on the studies mentioned, which, although minor problems have been experienced in the animal feeding study, *show no indications to date that reflect adversely on the wholesomeness of radappertized beef.*

# APPENDIX C

DEPARTMENT OF THE ARMY
OFFICE OF THE DEPUTY CHIEF OF STAFF
FOR RESEARCH, DEVELOPMENT, AND ACQUISITION
WASHINGTON, D.C. 20310

REPLY TO
ATTENTION OF:

12 Aug 70

Dear Mr. Price:

This letter is a reply to your letter of 6 July 1970 requesting information relative to the food irradiation program being conducted by the Army.

We have carefully reviewed our program planned for FY 71 through FY 75. Participating in this review was the Commanding Officer, Natick Laboratories, his Scientific Director, and his Associate Director for Food Irradiation. Based on their recommendations we have decided to increase our planned fiscal support to assure retaining a stronger capability for reinstatement of the developmental effort should success in proving wholesomeness justify that course of action. In order of priority the program provides for first, the crucial task of proving wholesomeness; second, for maintaining the essential technological staff; and third, for resumption of large scale production oriented developmental efforts at some future date. The summary at Inclosure 1 shows the increases and provides more information on the planned allocation of funds. The man hours associated with each planned effort are shown at Inclosure 2.

We believe that the program as now constituted meets your objectives. We believe it is only prudent at this time to proceed through wholesomeness verification with a single food. During the course of the coming years we will be in a position to change the program in the light of the results. We can either (1) expand the number of foods in the wholesomeness phase, (2) expand the technical effort to solve problems if they arise during the wholesomeness study of the first food, (3) add funding to develop specific food items for commercial application if the wholesomeness results justify that course, or (4) terminate the program should unsolvable problems appear.

There may be some misunderstanding on the matter of medical management of the wholesomeness program. It is our feeling that we can do a better job by assigning the best medical personnel available from the limited resources of the Surgeon General to concentrate on one wholesomeness program rather than dilute the effort on multiple studies at a time which is crucial in terms of public opinion and FDA attitudes. While, of course, there are shortages in medical personnel, the Surgeon General has assured us that he will provide people needed to properly oversee this important work.

With the plan now established we believe that we have provided for sound experimental procedures, adequate management of the contract effort, and appropriate time and money for the critical wholesomeness study on the results of which all else depends. We believe that more money above the funds we are planning would not help at this time. The block to full implementation remains wholesomeness and our program is designed to resolve the remaining questions on safety and nutritional adequacy of foods preserved by high dose sterilization. Since FDA has raised these questions and must, in the last analysis, grant the final approval, we must react to their desires, recommendations and suggestions. Once they have been resolved favorably we are in a position to move forward rapidly. Should satisfying their requirements ultimately prove impossible, we will not have been over committed with production plans which cannot be used.

In summary the Army finds itself under pressure on the one hand from a group that is completely convinced that high dose sterilization is safe and on the other inhibited by those who have fears that it may not be. We propose to do the best we can to bring these groups together. We believe that the program as outlined in this letter is well designed to do just that. We appreciate your support and the interest you have shown in this program from its inception.

Sincerely,

(Signed)
Stanley R. Resor
Secretary of the Army

2 Incls
a/s

Honorable Melvin Price
Chairman, Subcommittee No. 3
Committee on Armed Services
House of Representatives
Washington, D. C. 20515

FISCAL SUMMARY OF THE PLANNED ARMY FOOD IRRADIATION STERILIZATION RESEARCH PROGRAM - FISCAL YEARS 1971 THROUGH 1975

1970

(Proposed funds in thousands of dollars)

| | Fiscal Year | | | | |
|---|---|---|---|---|---|
| | 1971 | 1972 | 1973 | 1974 | 1975 |
| Technical Feasibility of Meat, Pountry, and Marine Products | 45 | *(1) | * | * | * |
| Assurance of Wholesomeness | 1000 | 1000 | 1000 | 1000 | 1000 |
| Flexible Packaging | 47 | * | * | * | * |
| Adaptation to Military Needs | 80 | * | * | * | * |
| Basic Food Irradiation Research | (3)169 | 250 | 250 | 250 | 250 |
| Radiation Services (3) | 248 | 689(2) | 339 | 339 | 339 |
| Development of Irradiated Foods | 140 | 140 | 140 | 140 | 140 |
| Total Project Tasks | 1729 | 2079 | 1729 | 1729 | 1729 |
| Facilities & Installation Support | 310 | 310 | 310 | 310 | 310 |
| TOTAL | 2039 | 2389 | 2039 | 2039 | 2039 |

Notes (1) Asterisk entries indicate no funds are presently assigned. Future allocation of funds depends upon success in the wholesomeness studies.

(2) This funding level includes 350 thousand dollars in FY 72 for cobalt source replenishment and equipment.

(3) These tasks provide for the maintenance of the unique staff and the conduct of required technical efforts.

TASK DISTRIBUTION OF TECHNICAL MANPOWER
FOOD IRRADIATION PROGRAM - US ARMY NATICK LABORATORIES

| Task | Man-Years | | | | |
|---|---|---|---|---|---|
| | FY 71 | FY 72 | FY 73 | FY 74 | FY 75 |
| Technical Feasibility of Meat, Pountry, and Marine Products | 3 | * (1) | * | * | * |
| Flexible Packaging | 3 | * | * | * | * |
| Adaptation to Military Needs | 2 | * | * | * | * |
| Basic Food Irradiation Research | 6.5 | 11.5 | 11.5 | 11.5 | 11.5 |
| Radiation Services | 15 | 18 | 18 | 25 | 25 |
| Development of Irradiated Foods | 7 | 7 | 7 | * | * |
| Totals | 36.5 | 36.5 | 36.5 | 36.5 | 36.5 |

Notes (1) Asterisk entries indicate amount of effort cannot now be determined. Future effort application depends upon success in wholesomeness studies.

# APPENDIX D

DEPARTMENT OF THE ARMY
ARMY SCIENTIFIC ADVISORY PANEL
Washington, D. C. 20310

5 February 1975

Membership
AD HOC GROUP
on

Irradiated Food Program

Chairman

Dr. Chris J. D. Zarafonetis
Simpson Memorial Institute
The University of Michigan
102 Observatory Street
Ann Arbor, Michigan 48104
(Area Code 313 764-8100)

Military Staff Assistant

LTC Dennis S. Farley
Office, Deputy Chief of Staff for
Research, Development, & Acquisition
ATTN: DAMA-CSS-D
Washington, DC 20310
(Area Code 202 695-0819)

Members

Dean Kenneth E. Clark
College of Arts and Science
University of Rochester
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(Area Code 716 275-2351)

Dean Ralph E. Fadum
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North Carolina State University
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Medical Consultant
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(Area Code 301 530-7552)

Special Consultant

Dr. Raymond Cooper
Division of Bio Medical and
Environmental Research
Energy Research & Development
Administration
Germantown Building, Rm 2E 201
Washington, D. C. 20545
(Area Code 301 973-3631)

# APPENDIX E

DAMA-CSS 14 February 1975

MEMORANDUM FOR THE RECORD

SUBJECT: First Meeting - Ad Hoc (ASAP) Committee for Irradiated Food Program

1. The first meeting of the Ad Hoc Committee for the Irradiated Food Program was held at 0900 hours, 13 February 1975 in room 3D434, Pentagon, Washington, D.C.

2. Attendees:

Committee

| | | |
|---|---|---|
| Dr. Chris J. D. Zarafonetis | - | Chairman |
| Dean Ralph E. Fadum | - | Member |
| Dr. Raymond Cooper | - | Special Consultant |
| LTC Dennis S. Farley | - | Military Staff Assistant |

Briefers

| | | |
|---|---|---|
| Dr. Corbin I. Miles | - | Food and Drug Administration |
| Dr. Edward S. Josephson | - | Natick Laboratories |
| COL Roger Baker, VC | - | Medical R&D Command |

Observer

| | | |
|---|---|---|
| Dr. William Daniel | - | Army Materiel Command |

3. Proceedings:

a. The chairman opened the meeting by welcoming those in attendance and then outlining the purposes for the ad hoc committee and for this first session.

b. The military staff assistant provided each committee member with a book containing several articles of background information.

c. The first briefer of the day was Dr. Corbin I. Miles, from the office of Food Additives, Food and Drug Administration, who discussed the FDA regulations covering food additives and wholesomeness testing. (A copy of Dr. Miles comments will be provided to the committee, when they are made available by the FDA).

d. The next briefer was Dr. Edward S. Josephson, Deputy Technical Director, Food Service Systems Program, Natick Laboratories. Dr. Josephson presented a brief history of the irradiated food program within the Army, its relation-

ship with the national and international programs, and provided the background of events leading up to the current wholesomeness testing of beef. Dr. Josephson agreed to provide the committee several items of information upon his return to NLABS.

e. The final speaker of the day was Colonel Roger Baker, VC, Special Project Officer for Wholesomeness Testing, Medical R&D Command, who discussed the beef wholesomeness testing program. (A copy of his presentation is item "S" in the book of articles provided by the military staff assistant.)

f. Following a lunch break, the committee met and determined that:

They would hold their next meeting on 6 March 1975 at the Pentagon. Speakers to be invited would be Dr. Shulman, Energy Research and Development Agency (to be invited by Dr. Cooper); Dr. Joseph Coates, Office of Technological Assessment (to be invited by Dean Fadum); Mr. Bloom, State Department (to be invited by LTC Farley); and Dr. Brown, Chairman of the NRC Committee on Irradiated Foods at Natick Laboratories (to be invited by LTC Farley). The committee also agreed upon 21 March as the tentative date for the "working" session to prepare the committee report.

4. The meeting adjourned at 1430 hours.

SIGNED

DENNIS S. FARLEY
LTC, GS
Military Staff Assistant

# APPENDIX F

DAMA-CSS

MEMORANDUM FOR THE RECORD

SUBJECT: Second Meeting - Ad Hoc (ASAP) Group on Irradiated Food Program

1. The second meeting of the Ad Hoc Group on the Irradiated Food Program was held at 0900 hours, 6 March 1975 in room 1E801, Pentagon, Washington, D.C.

2. Attendees:

Committee

| | | |
|---|---|---|
| Dr. Chris J. D. Zarafonetis | - | Chairman |
| Dean Ralph E. Fadum | - | Member |
| Dr. Herbert L. Ley, Jr. | - | Member |
| Dr. Raymond Cooper | - | Special Consultant |
| LTC Dennis S. Farley | - | Military Staff Assistant |

Briefers

| | | |
|---|---|---|
| Mr. Justin Bloom | - | Department of State |
| Dr. David Bruner | - | Department of State |
| Dr. William Brown | - | Chairman, NRC Committee on Irradiated Food, NLABS. |
| Dr. Pat Johnson | - | National Science Foundation |
| Dr. Murray Schulman | - | Energy Research & Development Administration |

3. Proceedings: (Agenda is attached)

a. The chairman opened the meeting by welcoming the attendees. Based upon approval from the group members present, the MFR of the first meeting was accepted as the official record of those proceedings.

b. The first briefer was Mr. Justin Bloom from the State Department, who had worked for years, in various agencies, on the irradiated food program, and currently was assigned to the Bureau of International Scientific and Technological Affairs. Mr. Bloom brought Dr. David Bruner along with him, who is an assistant to Dr. Dixie Ray, Assistant Secretary of State for Oceans, Environment and Scientific Matters. In addition to high-lighting the history of and interest in food irradiation on a world wide basis, Mr. Bloom also indicated that Dr. Ray was very much in support of this rogram and had offered the services of her office and those of her public relations officer (Mr. Guzzo) in promoting the program. In addition, Mr. Bloom indicated that: "If we are going to make progress internationally, we must make commercial adaptation/success here." In response to questions, Dr. Bruner

indicated that once safety of the equipment/process was shown, it would be wiser to export the "system," in total to underdeveloped countries, than to process foods here and then export. It was emphasized that the entire system, to include transportation and distribution of processed product was needed.

c. Dr. Brown outlined for the group the advantages of this system to industry, indicating that the principle advantages were that irradiation was a "cold" process, thus producing a better product and it did not require freezing/refrigeration storage of the processed product. He also discussed the advantages this process had on controlling disease/health problem micro-organisms and agents. Dr. Brown agreed to provide a paper which contained the main points of his presentation.

d. Dr. Pat Johnson presented the group a thorough outline of technology assessments, their applications and implications. Based upon his brief observations at this meeting, Dr. Johnson indicated that he believed we were probably most interested in a "problem originated" technology assessment, as opposed to a "technology or project originated" type. He informed the committee that the National Science Foundation or the Congressional Office of Technology Assessment could undertake such an assessment for the DOD, and that it could cost between $300-400K and take approximately 12-18 months. He indicated that any assessment, to be meaningful would have to include international factors. He also warned that the sponsor of such an effort would have to be prepared for the "results" of such an assessment, since they did not always result in "good news" and the results did become public knowledge. Dr. Johnson provided the group with several excellent books on technology assessment and also several published assessments.

e. Dr. Schulman, a radiation biologist, who for years worked for the Atomic Energy Commission, and now is employed with ERDA, indicated that ERDA's efforts and interest in food irradiation has dwindled to a $100K per year effort. He indicated that the AEC effort was always oriented towards the international application of the technology, and as a result they joined 21 other countries in an international project to conduct wholesomeness studies on low dose applications to food items. Fish currently is the principal food item being tested. (This is the "Last" major item ERDA has a commitment to Congress for). Dr. Schulman, in addition to providing the committees with copies of several of his recent international presentations, outlined these recommendations.

(1) There are not enough products being adopted; (2) the present beef protocol needs to be streamlined - you could get by with 1/3 of effort currently being expended; (3) the medical command has only part time workers on wholesomeness, they should have a full time effort; (4) and the Army should not rely only on in-house experts for review of their program/protocols. They

should instead bring in international experts, along with FDA to review new protocols. Dr. Schulman then identified several of these experts for the committee.

f. Following a lunch break, the committee met and determined:

(1) They would hold the next meeting on 20 March 1976 to work on the final report.

(2) That the military staff assistant would prepare and distribute a "draft" report prior to the meeting on the 20th, which would serve as a base for development of the final report.

4. The meeting adjourned at 1500 hours.

Signed:

1 Incl
as

DENNIS S. FARLEY
LTC, GS
Military Staff Assistant

AGENDA

AD HOC COMMITTEE (ASAP)

"IRRADIATED FOOD PROGRAM"

SECOND SESSION

6 March 1975

| | | |
|---|---|---|
| 0900-0920 | Welcoming and administrative comments | Chairman |
| 0920-1000 | International implications of irradiated foods | Mr. Justin Bloom State Department |
| 100-1040 | Technology Assessments | Dr. Pat Johnson National Science Foundation |
| 1040-1100 | Coffee Break | |
| 1100-1140 | National Research Council Impressions of the irradiated food program at the US Army Natick Laboratories | Dr. Wm. Brown Chairman, NBC Comm. on Irrad. Food, NLIBS |
| 1140-1220 | Food irradiation program at the Energy Research & Development Agency | Dr. Murray Schulman ERDA |
| 1220-1330 | Lunch | |
| 1330-1500 | Executive Session | Chairman |
| 1500- | Adjournment | |