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The Development of Irradiated Foods for Immuno-Compromised Patients and other Potential Target Groups

REPORT OF THE FIRST RESEARCH COORDINATION MEETING

Vienna, 23-27 August 2010

FAO / IAEA Division of Nuclear Techniques in Food and Agriculture

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INTERNATIONAL ATOMIC ENERGY AGENCY

Report of the First Research Coordination Meeting

On

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1. Introduction

The first Research Coordination Meeting (RCM) of the Coordinated Research Project (CRP) on the Development of Irradiated Foods for Immuno-Compromised Patients and other Potential Target Groups met at the IAEA Headquarters in Vienna, Austria, from 23 – 27 August 2010.

The meeting recalled that the overall objective is to utilise irradiation technology to increase the variety, availability and acceptability of foods for immuno-compromised patients and other potential target groups with special dietary needs. This will involve participants working in collaboration with their healthcare community and target groups to research appropriate foods, for example irradiated fresh produce (fruits, vegetables, salads), ready-to-eat meals (ethnic or locally produced) and functional foods. An allied objective is to generate data on the acceptability of irradiated foods in terms of both quantitative factors (microbiological safety, nutritional and organoleptic properties) and qualitative properties (psychological well-being, quality of life). Secondary objectives include the development of microbiological criteria for foods intended for different target groups of patients based on the microorganisms of importance and dietary requirements.

The meeting was chaired by Suresh Pillai. The administrative secretary was Stella Attakpah and the scientific secretary was Carl Blackburn. The list of participants and adopted agenda are attached at Annex A and B, respectively. A research protocol was adopted that contains guideline microbiological levels for foods intended for immuno-compromised patients and other potential target groups (Annex C) and the types of foods to be researched by CRP participants are summarized (Annex D).

2. Background

Food irradiation is one of the few technologies which address both food quality and safety by virtue of its ability to control spoilage and food borne pathogenic microorganisms without significantly affecting sensory or other organoleptic attributes of the food. Foods are irradiated to provide the same benefits as when they are processed by heat, refrigeration, freezing or treatment with chemicals, but irradiation has several advantages:

- It does not significantly raise food temperature and the food does not "cook".
- Unlike chemical treatments, irradiation does not leave potentially harmful residues.
- It can be used to treat packaged food, which will remain safe and protected from microbial contamination after treatment.

After many years of research and the development of national and international standards, more than 60 countries have regulations allowing food irradiation of at least one product. Commercial food irradiation is normally applied in combination with other food processing technologies at radiation doses of less than 10 kilogray (kGy). This degree of irradiation destroys populations of microorganisms, including disease-carrying bacteria and spoilage organisms. The food is not completely sterilized, but the many-fold reduction in microorganisms helps prevent illnesses and also makes it possible to keep food longer. Using irradiation to completely sterilize food is unusual, but high-dose treatments above 10 kGy have been used to sterilize food for non-commercial applications, for example in space programmes where irradiated, shelf-stable food products are provided for astronauts.

Ensuring food safety is especially important for people who have impaired immune systems, such as those who are immuno-compromised by disease (e.g. neutropenic patients) or who have recently undergone medical treatments (e.g. organ transplant patients). Food is a potential source of infection and even organisms normally considered non-pathogenic may cause problems. Three safety levels of diet are generally recognised by healthcare professionals:

- Sterile diet.
- Clean (low bacterial count or neutropenic) diet.
- Normal common sense food hygiene.

Health care trends have moved away from stringent sterile diets towards clean diets where there are advantages in maintaining exposure to normal microbial flora, with the added advantage of having a greater dietary variety. The clean diet approach ensures good hygiene practices are observed and imposes restrictions on foods that are known to be unsafe. The risk of food borne illness, though not completely eliminated, is minimised to an acceptable degree.

Despite the potential for food irradiation to provide food that is sterile or clean, there is little evidence of its wide-scale use to provide food for patients or other potential target groups who require this level of food safety. Recent research undertaken under a CRP[1] (2002-2006) on the use of irradiation to ensure the safety and quality of prepared meals established that ionizing radiation, in combination with good manufacturing practices and refrigeration, greatly reduces the risk of food-borne diseases in a wide variety of foods, and results in both nutritional and psychological benefits for immuno-compromised patients. However, as this was the first research carried out under a CRP related to the use of food irradiation for immuno-compromised patients, it was concluded that more research should be undertaken to widen the meal variety and to explain this method to the medical community, including patients, health institutes and catering services. In addition, collaboration between food irradiation researchers and nutritionists was considered essential to ensure the acceptance and to advance regulatory initiatives related to the use of food irradiation for these purposes. It was further concluded that the commercial availability of these shelf-stable foods would enable hospitals, without specialist catering facilities, to provide clean diets.

A Consultants Meeting was held at the IAEA Headquarters in Vienna from 24 – 27 November 2009 in order to consider the application of irradiation technology to foods for patients and other target groups. The purpose of the Consultants Meeting was to advise the Food and Environmental Protection subprogramme of the Joint FAO/IAEA Programme of Nuclear Techniques in Food and Agriculture (NAFA) on a proposed Coordinated Research Project (CRP) on the use of irradiation for shelf-stable sterile foods for immuno-compromised patients and other specific target groups. The Consultants Meeting recommended that:

(i) The CRP should primarily concentrate on foods for immuno-compromised patients as well as other potential target groups.

(ii) CRP participants should investigate and develop irradiated foods for immuno-compromised patients and other target groups in collaboration with other relevant partners, including medical doctors, nutritionists, other healthcare food industry specialists and relevant international organizations. The title of the CRP should be revised to the "Development of Irradiated Foods for Immuno-compromised Patients and Other Potential Target Groups".

(iii) CRP participants must have access to, or be able to undertake:

- Radiation processing (gamma, X-ray or electron beam).
- Quantitative microbiological, nutritional and sensory testing.
- Qualitative psychological assessments.

(iv) The CRP should mainly investigate irradiated foods such as fresh produce (fruits, vegetables, salads), ready-to-eat meals (chilled packed meals) and functional foods. Studies should take into consideration ethnic, local and regional foods.

(v) The first RCM should:

- Establish a range of diverse foods for study.
- Agree which organisms are of importance, including viruses, bacteria and parasites.
- Determine appropriate microbial criteria for the foods under development.

(vi) Studies should take account of the specific target group of patients and any related factors such as age, additional special dietary requirements (low salt, low protein, low fat), and specific feeding requirements (e.g. orally or nasogastric).

[1] Irradiation to Ensure the Safety and Quality of Prepared Meals, IAEA 2009, ISBN 978-92-0-111108-1

(vii) The CRP should include an educational element on irradiated therapeutic food, which should be targeted at medical specialists. The collation and dissemination of appropriate information and data should form part of this activity, as should patient surveys regarding the acceptability of irradiated foods in hospital diets.

The participants of this first RCM agreed with these recommendations and incorporated them into their respective work plans. The range of foods for study, the organisms of importance, microbiological criteria, and experimental approach were also discussed and agreed.

3. Objectives of the Coordinated Research Project

The overall objective is to utilize irradiation technology to increase the variety, availability and acceptability of foods for immuno-compromised patients and other potential target groups with special dietary needs, for example irradiated fresh produce (fruits, vegetables, salads), ready-to-eat meals (ethnic or locally produced) and functional foods. The allied objective is to generate data on the acceptability of irradiated foods in terms of both quantitative factors (microbiological safety, nutritional and organoleptic properties) and qualitative properties (psychological well-being, quality of life).

The specific objective of the CRP is to research a range of simple irradiated foods (fresh fruits, vegetables and salads) and complex irradiated foods (ready-to-eat meals) for immuno-compromised patients and potentially other target groups.

Secondary objectives include the development of microbiological criteria for foods intended for different groups based on the bacterial organisms of importance and dietary requirements as related to different age groups (infants, children, adults and the elderly). The acceptance of irradiated foods by the healthcare and regulatory communities will increase the development, marketing and commercialization of irradiated foods for hospital patients. This project could also lead to the use of irradiated foods by other potential target groups (e.g. space food, civil defence, outdoor activities).

Expected Research Outputs

- Data on the:

  (i) microbiological, nutritional and organoleptic properties of irradiated foods for patients.

  (ii) acceptability of irradiated foods for patients, hospitals, medical professionals and other potential target groups.

  (iii) use of ionizing radiation in combination with other food technologies such as Modified Atmosphere Packaging (MAP).

- The publication of:

  (i) research data on the applicability of food irradiation for medical diets.

  (ii) educational and informational material for healthcare specialists, consumers and other relevant stakeholders.

  (iii) an FAO/IAEA Technical document (TECHDOC) for use by the medical community and other relevant parties, including in the development of future Technical Cooperation projects.

Expected Research Outcomes

It is expected that:

- the information provided by this CRP will enable the socio-economic potential of irradiated foods for these target groups to be realized (i.e. the potential to market irradiated foods and for patients to benefit from availability of this food).

- irradiated fresh produce (fruits, vegetables, salads), ready-to-eat meals (ethnic or locally produced) and functional foods, will be made available to the medical community, immuno-compromised patients and other potential target groups.
- microbiological, nutritional and organoleptic information generated by this CRP will be available to others and used to develop specific criteria for foods for different patients.
- irradiated food will be accepted by hospitals, medical professionals, patients and other potential target groups.
- there will be increased knowledge on the acceptance of irradiated foods.

The meeting noted that this CRP provides a unique opportunity to generate benchmark microbiological criteria and data for foods for medical patients and others.

4. Objectives of the First Research Coordination Meeting

The objectives of this first RCM were to refine the work plans and activities to be undertaken during the course of the CRP and provide a better understanding of the CRP objectives as well as agreeing upon a common approach for moving forward.

In particular, the meeting was convened to:

- Discuss the proposed research plans of individual participants.
- Facilitate a broader understanding of the relationship each has to the overall objectives of the CRP.
- Promote interaction between the participants.
- Prepare a set of recommendations and guidelines to facilitate and promote the CRP objectives and project tasks.

5. RCM Presentations

David Byron, Head of Food and Environmental Protection Section informed the meeting of international initiatives related to applications of food irradiation, including activities of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture (NAFA), and specifically the Joint Division subprogramme on Improving Food Safety and Consumer Protection. The Food and Environmental Protection Section of the Joint Programme and its associated Food and Environmental Protection Laboratory of the FAO/IAEA Agricultural and Biotechnology Laboratory in Seibersdorf provide assistance and support to countries in their efforts to ensure the safety and quality of food and agricultural commodities while at the same time facilitating international trade[2].

Christine Slater, Nutrition and Health-Related Environmental Studies Section of the Division of Human Health, gave an outline of the work carried out under the subprogramme on Nutritional and Health-Related Environmental Studies. This work can be divided into three main areas, all of which have a common basis in using nuclear and isotopic techniques to help improve human health through better nutrition and through protection of selected populations from the deleterious effects of environmental pollution[3]. Chrisitne has experience of irradiating food for hospital patients and provided the meeting with information on her previous work to irradiate food for a hospital.

Bashur Bashur, IAEA Department of Nuclear Sciences and Applications, Research Contracts Administration Section, provided information on the purpose of coordinated research and the role of the IAEA[4] with

[2] http://www-naweb.iaea.org/nafa/fep/index.html
[3] http://www-naweb.iaea.org/nahu/nahres/default.shtm
[4] http://www-crp.iaea.org/html/sitemap.html

particular emphasis on CRP research activities. This included a discussion on how a CRP is developed in relation to a defined research topic on which an appropriate number of institutions are invited to collaborate. A CRP is an effective means of bringing together researchers in both developing and industrialized countries in order to solve a problem of common interest. There are usually two main types of contractual arrangements under a CRP and these are (i) Research Contracts and (ii) Research Agreements. Preference in the award of Research Contracts is given to institutions in developing countries. Research Contracts are awarded to contribute towards funding research activities for an initial duration of one year with the possibility of renewal. In contrast, a Research Agreement does not provide financial support, but is awarded to institutions that agree to provide a report at each Research Coordination Meeting on work relating to the CRP and to assist other participants where necessary. In return, the Research Agreement holder shares in the results of the work of all participating institutions.

Research Contract Holder Presentations

Widening the Meals Variety for Immunocompromised Persons and Other Target Groups by Ionizing Radiation

Maria Constanza Cova, Argentina

Background

Research under a previous CRP took into account medical criteria, and the drive away from "sterile foods" to "clean diets". Ionizing radiation at sub-sterilizing doses was employed to irradiate food and determine the feasibility of broadening the variety of meals available for immuno-compromised patients. Irradiation technology allowed their diets to include some products normally considered "high risk", but otherwise nutritionally or psychologically adequate. The foods studied were salads, ice-cream and cannelloni (CRP 1999-2000).

Microbiological and sensory analyses were performed by a consumer panel throughout the product storage time and results were found to be acceptable. A second phase of research studied different commercial ready-to-eat-meals, and challenge microbiological tests were performed involving inoculation with highly radioresistant non-sporulated pathogens in order to determine the minimum radiation dose able to achieve a 6 log cycle reduction in viable counts. Irradiated samples were checked against control samples in order to monitor their microbiological and sensory quality with storage time. Irradiation decontaminated the food without significantly impairing its sensory quality and the storage life of irradiated samples was extended by approximately threefold by comparison to non-irradiated control samples.

In the final phase, a complete lunch menu was designed by nutritionists; it was composed of mixed salad, "empanadas" (typical Argentine dish with meat, vegetables and pastry) and fresh fruit salad in gelatine with white cheese. Control and irradiated menus were tested by a "healthy" consumer taste panel and found to be acceptable. The irradiated menu was found to have a storage life extension of almost three-fold (in agreement with previous findings). Sensory testing was also performed by a panel of immuno-compromised patients at the Teaching Hospital "Jose de San Martin", Buenos Aires. These patients liked the irradiated lunch very much, their taste scores were significantly higher than the "healthy panel", and this could have been because these types of foods had been excluded from their recent diet (e.g. one patient volunteered to take part in this study because she was fond of salad and had not been allowed to eat salad for the previous three months). The patients were enthusiastic about this research and asked for the irradiated menu and other similar irradiated dishes to be made commercially available (CRP 2002-2006).

(ii) Planned activities for the first stage of this new CRP include:

Planned activities were summarized as:

- Survey by nutritionists for inmmuno-compromised persons to learn about their preferences and evaluate meals adequateness.
- Developing food which could benefit from the irradiation treatment, such as raw foods (fresh produce), and undercooked foods with with cross contamination risks. If necessary, combining irradiation with other methods (heating, storage temperature, MAP, edible coatings, additives, etc.) to ensure food quality is optimized after the irradiation treatment.

- Evaluating the effectiveness of irradiation as a method to ensure microbiological safety and extend shelf-life of such foods, stored either under ambient, chilled or frozen conditions. Validated methods for microbiological determination and validated procedures for irradiation, process control and sensory evaluation will be used.
- Evaluating the sensory quality of the treated products over storage time with:
    - A "healthy" consumer panel: In order to determine acceptability and determine if there are significant differences between the control and the irradiated samples.
    - A panel of immuno-compromised patients: In order to determine acceptability of these irradiated samples to the specific target groups.

(iii) Contributionto the CRP objectives include:
- increasing the body of knowledge concerning foods which could benefit from irradiation treatments.
- Establishing contacts and promulgating findings to the medical and nutritionist communities.
- Offering irradiated meals and having them taste tested by immuno-compromised people.
- Attracting the interest of the food industry and hospital catering services with the purpose of encouraging future commercial implementation of the technology.
- Bringing this approach to the attention of national health regulatory agencies will also contribute to irradiated food being allowed more generally for immuno-compromised people.

Use of Irradiation for Shelf Stable Sterile Foods for Immunocompromised Patients and Other Specific Groups

Mohammad Alam, Bangladesh

Previous research has examined the preservation of semi-perishable foods and the development of convenience food products using a combination of irradiation and other physicochemical treatments. For example, the microbiological quality of fish kebabs sold in the open at street-side or by fast-food shops has been found to be poor, e.g. contaminated with enteric bacteria like E. coli. Studies have investigated the improvement in microbiological quality of sealed, ready to eat, commercially prepared fish kebabs by using a combination of gamma irradiation with spices and an acidulant (such as ascorbic acid). Laboratory studies of packs inoculated with Clostridium botulinum have also shown that when oil fried, the irradiated kebabs had improved heat penetration, and as a consequence spore formation was reduced (spores were eliminated in fried kebabs that had been irradiated to 5 kGy). It was observed that using a combination of processes is more effective than a single treatment for the preservation of semidried and convenience food.

Immunocompromised hospital patients are estimated to be 20% of the total world population. So it is important to supply safe and sterile foods specifically for these patients. Our target is to develop ready to eat prepared food for immunocompromised patients as well as other target groups. Due to the lack of national dietary guidelines, no specific food is properly prescribed for such patients in Bangladesh. Dietary composition in respect of protein, carbohydrate and fat depend on the type of patients. Our objectives to meet the present CRP target is to:

- survey some potential target hospitals.
- discuss the issue with the dieticians and physicians concerned.
- select a specific target group and prepare food for this patient group (e.g. kidney disease or neutropenia).
- research and optimise the microbiological and organoleptic changes to the food.
- supply prepared food to targeted hospitals and follow up with the patients.

Application of Ionizing Radiation: Foods for People with Specific Diets

Susy Frey Sabato, Brazil

Background

People with immune-compromised systems cannot eat several types of food because of the associated high risk of infection. Among these foods are fruits, vegetables, raw eggs and food made with them, raw fish, unpackaged and undercooked meats, unpasteurized creams and cheeses, ice-cream, uncooked nuts, and dried

fruits. One way to overcome this situation is the use of ionizing radiation applied to food. Food irradiation processing has been studied for over 40 years, it is proven to reduce microbial load whilst ensuring minimal organoleptic changes. Consequently, food irradiation could be beneficial to society in general and in particular to immuno-compromised patients who require high sanitary standards and whose diets are currently restricted to heat treated foods. In Brazil, this approach is very innovative.

Planned Activities
This project will cover the research and developments of meals, which due to the normal risk of adverse microbiological contamination, are not usualy served to immuno-compromised patients (i.e. fresh vegetables, fruit salads and ice creams). Irradiated meals will be evaluated microbiologically and some specific nutritional and physical-chemical properties will be analyzed. Sensory evaluation will be carried out in order to verify the acceptance of irradiated meals.

Objectives
The overall objective is to generate data on the effectiveness of irradiation to improve the microbiological safety and quality of some specific meals, comprising foods which are not normally served to immune-compromised patients.

Specific objectives are:
- Development of food in suitable packaging from which it can be served and as required by our collaborating hospital, the Hospital das Clínicas - HC (Brazil's main hospital, located in São Paulo).
- researching the microbiology of the food as irradiated to ensure that specific requirements for patients are respected.
- Studying physical, chemical and nutrition aspects that are relevant for certain foods.
- Sensory evaluations of irradiated food will be carried out in order to verify its acceptability.
- The production of guidelines to be provided along with the food advising on the appropriate use of the food/packaging.
- Dissemination of the results to nutritionists and hospitals.

Use of Irradiation for Low Salt Chinese Traditional Pickles for Immuno-Compromised Patients

Gao Meixu, China

Meixu Gao, from the Institute for Application of Atomic Energy, Chinese Academy of Agricultural Sciences, has worked on food irradiation for more than 20 years. Her recent research work focused on irradiation to lower the allergenicityof shrimp protein and crab protein, irradiation application for new food items (e.g. fermented foods), and the application of electron beam irradiation to food.

The work plan for the first year of research is:
- To undertake a literature study and market evaluation of Chinese pickle products in order to determine which would be most likely to be the suitable for research and consumed by immuno-compromised patients in China.
- perform microbiological tests of selected pickles, using standard methods.
- Evaluate the irradiation tolerance of each pickle (the result will be used to determine if irradiation in combination with other food technologies is necessary).
- Undertake tests on irradiated pickles (microbiological tests, sensory testing and nutrient analysis as necessary).

The aim of this research is to provide more dietary variety for immuno-compromised patients and enhance the application of food irradiation as a treatment to ensure food safety. This will contribute to the objectives of the CRP.

Use of Irradiation to Provide a Wider Selection of Safe, Nutritionally and Organoleptically Adequate Foods for Immuno-Compromised Patients

Csilla Mohacsi-Farkas, Hungary

Background

The work will be carried out by the Faculty of Food Science, Corvinus University of Budapest in collaboration with National Institute for Food and Nutrition Science, Hungary. This partnership has experience in food microbiology, analysis of chemical components of food as well as in nutritional science. Participation in previous CRPs on the use of irradiation to ensure safety and quality of ready-to-eat meals and fresh cut/prepared produce provide good background for further successful research work.

Planned Activities

The aim of the project is to use irradiation to provide a wider selection of safe, nutritionally and organoleptically adequate foods for immuno-compromised patients. Surveys will be carried out to collect data on the dietary recommendations and on institutional practices for dietary restrictions for different categories of immuno-suppressed patients. Sensorially acceptable maximal radiation doses for fresh, pre-cut, prepared fruits and vegetables, ready-to-eat meals and dairy products/desserts, fruit jellies will be established. Food items will be selected to meet both the dietary recommendations of medical experts and requirements of patients. Examination of changes of the "native" microflora, and the nutritional and organoleptic properties of irradiated food items will be performed. Reduction of specific food-borne pathogenic bacteria by gamma irradiation will be assessed in challenge studies to select the adequate processing doses. Research data on the use of gamma irradiation in combination with other preservation technologies, such as Modified Atmosphere Packaging or Sous-vide cooking to improve microbiological safety, nutritional and organoleptic quality of food items will be collected. Sensory analysis of irradiated, microbiologically safe meals by panels of healthy people and of immuno-compromised patients will be organized. Education of consumers, medical community and hospital patients about the safety and application of food irradiation technology is highly advised and planned.

The objectives of the proposed research will contribute directly to both the overall and specific objectives of the CRP.

Irradiated Foods For Immuno-Compromised Patients And Other Potential Target Groups In India

Arun Kumar Sharma, India

Food Technology Division (FTD), Bhabha Atomic Research Centre (BARC), is the leading R&D centre in the field of radiation processing of food in India. Through the basic and applied R&D of more than fifty years it has generated an excellent knowledge base for understanding the technology and its commercial exploitation in the areas of food security, safety and international trade. In the past few years, the FTD has focused on radiation preservation of ready-to-eat (RTE) intermediate moisture (IM) food products, ready-to-cook (RTC) minimally processed, cut and packed vegetables, development of protocols for quarantine treatment of fruits and applications of high dose radiation for improvement of food quality.

As a part of international collaborative efforts in the past, FTD has participated in several IAEA sponsored Coordinated Research Projects (CRPs) in different areas of food irradiation and welcomes this opportunity to participate in this new CRP on 'Irradiated Foods for Immuno-compromised Patients and Other Potential Target Groups'. India has the second largest population in the world, the number of immuno-compromised patients is steadily increasing due to increased incidence of diseases like cancer, HIV/AIDS, diabetes, and increase in age expectancy. There is a need to develop microbiologically safe and nutritionally wholesome food products for this segment of the population. Other groups needing such foods could include infants, pregnant mothers, aged people, astronauts, and adventurers.

The details of the nutritional, psychological and legal requirements of patients will be assessed in liaison with hospitals local to the research centre. Potential foods will be selected, and these target food products will be procured, packed and treated with radiation alone, or in combination with other conventional techniques. The foods will be tested for microbiological and nutritional attributes during storage, and further tested for organoleptic quality and consumer acceptance. Irradiation treatment protocols and standard operating procedures will be developed and could be used or adapted for use by industry for hospital supply in commercial settings. At the end of the CRP, it will be possible to meet the objectives as detailed in the CRP document.

Development of Safe Ethnic Foods - Irradiation for Specific Target Groups Including Immuno-Compromised Patients

Zubaidah Irawati Koenari, Indonesia

Food poisoning produces serious health consequences for specific target groups of people. Irradiation both at sterilization and sub-sterilization doses, either alone or in combination with other treatment, is a powerful tool to be used to provide foods that are suitable for specific target groups including immune-compromised patients. Some ethnic ready to eat foods have been successfully developed using high and medium irradiation doses under previous Coordinated Research Projects. This research activity can be developed further and implemented for the specific target groups in Indonesia, to improve the nutrition status and accelerate the recovery process of immune-compromised patients by increasing the range and variety of foods in their diets.

In this research, the ethnic ready-to-eat foods will be prepared (foods of both plant and animal origin). The formula, recipe, and product design will be developed in accordance with Indonesian Recommended Dietary Allowances (INS RDA) for specific target groups and include any additional special nutrients that may be required for immuno-compromised patients. The INS RDA is tabulated and based on age, gender, anthropometry data, energy requirements, and macro and micro-nutrient profiles. The preparation of a complete set of ready-to-eat foods will consist of 3 types of meals i.e., food appetizer (mixed vegetables/soup), basics/main meals (well cooked rice) and processed meats (fish/beef/chicken), and desserts (mixed fruits/ice cream/pudding/traditional desserts). The irradiation treatment employed for this purpose should not necessarily render products completely sterile, but result in low-microbe and pathogen free meals depending on the condition of patients. Food irradiation will be conducted under GRP and IAEA guidelines for producing sterilized and pasteurized ready to eat foods. Indonesia National Standards for processed foods and other international standards for sterility tests will also be implemented. The irradiation processing parameters and packing technique will be considered (the selection of packaging materials will consider Polyester/Al-foil/LLDPE, Nylon/PE, and banana leaf). Quality assessments of the irradiated foods will include microbiology, sterility, sensory, macro and micro nutrient analysis, pH, peroxide value, anti oxidant capacity, water activity, aflatoxin, etc. Samples will be evaluated before and during prolonged storage at room temperature (28-30^{o}C).

This research work will be carried out in collaboration with a range of scientists and professionals, including medical doctors, nutritionists, dieticians, food technologists, and microbiologists from different institutions. It is envisaged that this research will involve patients in a Therapy Unit and Rehabilitation Centre of the National Narcotics Bureau (NNB). An ethical clearance will be required prior to conducting this research and participants for consumer trails will be selected from volunteers using defined criteria, i.e, this will require informed consent agreements between respondents and researchers. The NNB Rehabilitation Centre, Indonesia is located in Bogor, West Java. Irradiated foods will be served to 3 different volunteer groups of patients in parallel with un-irradiated and regular foods as provided by the NNB canteen.

Selection of Irradiation Doses and Packaging Materials to Enhance Market Life of Hygienic Meals for Immuno-Compromised Patients and Other Target Groups

Anwar Ahmad, Pakistan

Dr Anwar Ahmad has been a research team member in all IAEA food related research contracts awarded to the Pakistan Nuclear Institute for Food and Agriculture (NIFA) since 1982. His research activities have

involved the standardization of gamma radiation doses for shelf life extension of different foods. He has also standardized different analytical techniques for the detection of irradiated dried fruits and tree nuts in trade during 1994-1998. Current work involves the preservation of various ready to eat ration type meals (MRE) by gamma radiation and improved packaging under vacuum. The main activities included formulation and preparation of different types of meals, selection of improved packaging, testing of simple and vacuum sealing, and standardization of gamma irradiation doses for shelf life extension.

Under this CRP, it is planned to achieve the objectives of the project by researching a set meal of legumes with chicken in the ratio of 75:25%, fortified with minerals and vitamin using natural resources. Herbal flavoured bread, fruit salad and herbal ice cream will also be prepared. The meals will be packed in three types of packaging materials (Tetra pack, Degradable plastic and Polyethylene pouches). The samples will be treated with gamma radiation to sterilization doses (doses above 10 kGy) if necessary. The samples will be tested and evaluated by physicochemical (protein, vitamins, peroxide, anisidine, pH), microbiological (spoilage and pathogenic organisms) and sensory (appearance, color, taste, flavor and overall acceptance) testing.

The planned research will fulfil the objectives of the CRP regarding the utilization of irradiation technology to increase the shelf life, availability and acceptability of foods for immuno-compromised patients and other potential target groups. In addition, the CRP will generate data on the acceptability of irradiated foods in terms of both quantitative factors (microbiological safety, nutritional and organoleptic properties) and qualitative properties (psychological well-being, quality of life). The planned research will also achieve the objective on the development of microbiological criteria for foods for various target groups of patients based on the bacterial organisms of importance and dietary requirements as related to different age groups (infants, children, adults and the elderly). Finally the acceptance of irradiated foods by the healthcare and regulatory communities will increase the development, marketing and commercialization of irradiated foods for hospital patients as well as space food, civil defence, and outdoor activities.

Development of Safe, Quality and Shelf-Stable Filipino Ethnic Foods for Immunocompromised Patients and Calamity Victims

Zenaida De Guzman, Philippines

Background

In the Philippines food irradiation studies have been undertaken on various commodities like spices, dehydrated vegetable products, fruits and grains. The technology has been proven to be an effective intervention method to provide safe and quality food by killing the pathogenic microorganisms and organisms that cause spoilage without significantly affecting food quality. In the Philippines there has been a limited amount of irradiation research on the efficacy of irradiation on shelf-life stable foods like meat and poultry products. The present study will examine the effects of irradiation on the quality safety and shelf-life extension of stable foods for specific target groups.

Planned activities

The proposed research will be towards developing shelf-stable Filipino ethnic foods through the use of radiation technology. The first phase of the study will be carried out to develop ready-to-eat foods and evaluate the effectiveness of the radiation process to treat foods and ensure they are suitable for immuno-compromised patients. The second phase aims to develop shelf-stable foods for calamity victims (i.e as rations for use in emergency food aid programs). Ethnic food products will be prepared, packaged, irradiated and evaluated for microbial, sensory and nutritional qualities. Protocols will be developed which detail the irradiation parameters necessary to treat these foods and the results of the study will be distributed to medical, scientific and food associations.

Objectives

- To develop Filipino ethnic foods using irradiation technology for the target patient groups.
- To conduct irradiation and packaging studies of the developed foods.
- To evaluate the microbiological, sensory and nutritional contents of the products.
- To develop protocols for the safe use of irradiation for shelf-stable foods.

- To evaluate consumers perception and acceptance of irradiated food and conduct information dissemination activities to the scientific and medical communities.

Combination Treatments Involving Irradiation in Order to Develop Shelf Stable Sterile Foods for Immuno-compromised Patients and Other Specific Target Groups
Samia Ayari, Tunisia

Previous research investigated the physiological responses of food borne pathogens (in broth) to gamma irradiation alone or in combination with other preservative techniques. Research results demonstrated that it is possible to radiosensitize bacteria using mild treatments already used by the food industry, thus enabling treatments to use lower irradiation dose than would otherwise be necessary and limiting the impact of higher irradiation doses on the quality of foods.

The application of irradiation in combination with other preservative technologies can contribute to addressing the pressing need for low microbial diets in a hospital environment for immuno-compromised patients and other target groups, with the added benefit that the product has a good organoleptic and nutritional quality. Low dose treatments (irradiation without complete sterilization) can be used to ensure food safety to immuno-compromised consumers. The combination of irradiation with other food processes is of potential importance in enhancing the effectiveness of the treatment through synergistic action, and reducing the energy or dose requirement of food preservation. Enabling lower dose treatments to be effective at treating food can therefore contribute to increasing the range of foods for the immuno-compromised.

During this CRP the objective is to develop the appropriate use of a mild irradiation treatment in combination with other food perseveration technologies, which can be used to substitute for the more severe application of irradiation treatment alone. Selected combined treatments will be applied and the antimicrobial effect will be evaluated against the food borne pathogen *Bacillus cereus* (vegetative form and spores) in vegetables and meat products. Microbiological, physico-chemical, nutritional and organoleptic properties will be determined in order to evaluate the acceptability by hospitals, medical and dietetic professionals.

Research Agreement Holder Presentations

Irradiation for Shelf Stable Sterile Foods for Immunocompromised Patients and Other Specific Target Groups
Ju-Woon Lee, Republic of Korea

The practical application and safety of food irradiation has been researched more than any other food processing technology. International agencies have recommended using irradiation technology to extend the shelf-life of foods, improve food safety and enhance food quality. Korea allows food irradiation of 26 types of foods treated to radiation doses below 10 kGy for the purposes international agencies have recommended. The Korea Atomic Energy Research Institute (KAERI) recently submitted a proposal to allow the irradiation of fresh meat, processed meat products and dried sea foods in Korea. The KAERI has also proposed that legislation enables the use of E-beam irradiation to treat foods (to add to Korean regulations that currently only allow gamma-irradiation of food).

Although scientific research has proved that the application of irradiation technology in the food industry is safe and practical, there is limited use of this technology due to perceived problems with consumer acceptance and this is an obstacle to the further development of commercial food irradiation. The application of irradiation technology to special purpose foods such as space foods, patient's meals, and survival rations could lead to improved understanding and acceptance by the general public, and this could open the way for more food products to be irradiated in future.

The KAERI has used high-dose irradiation technology to develop eight Korean "space-foods" for astronauts (Kimchi: fermented vegetable, Ramen: ready-to-cook noodles, Saengshik bar: raw grain bar, Sujeonggwa: cinnamon beverage, Bibimbap: cooked rice mixed with red pepper paste, Bulgogi: grilled beef marinated with soy sauce, Seaweed soup, Mulberry beverage), these irradiated products are certificated by the Russian

Institute of Biomedical Issues and could be commercialized. There has been a lot of media interest in these space foods and they are a good example to use when discussing the safety and quality of irradiated food with the public. Research experience gained in the development of space foods has been used at KAERI to develop foods for hospital patients and also rations. Usually, these foods need to meet stringent microbiological safety criteria with minimal changes to nutrients. Irradiation is capable of meeting this challenge and has been recommended as a method for preparing foods for hospital patients requiring sterile diets, especially for patients who have intensive therapy or disease that has suppressed their immune system. KAERI has employed irradiation to produce a sterile porridge for hospital patients. This food is high in calories and easy to digest due to decreased viscosity after irradiation. Moreover, a survey on this type of irradiated foods has been undertaken targeting patients, nutritionists and medical doctors in Korea. The survey results were favourable to the use of irradiation technology and the benefits it offers to patients. KAERI is making great effort to establish international collaborations to develop special-purposed foods and to commercialize them with member countries. Furthermore, KAERI is also researching the use of irradiation technology on development rations, which require long-term storage at ambient temperature with ensured microbial safety.

E-Beam irradiated diets for neutropenic bone marrow transplant recipients: technology and hospital food supply chain considerations.

Suresh Pillai, USA

The Research Agreement Holders Suresh Pillai and Karen Moody bring a unique combination of microbiology and paediatric oncology to this project. Suresh Pillai is a microbiologist by training with extensive experience in E-Beam irradiation technology. He heads the National Center for E-Beam Research at Texas A&M University and Professor of Microbiology at Texas A&M University. Karen Moody is the Director, Integrative Medicine & Palliative Care Team Section of Paediatric Haematology/Oncology Children's Hospital at Montefiore, New York. She is also the Assistant Professor of Paediatrics, Albert Einstein College of Medicine, New York

The planned activities in this CRP will focus on five major areas namely, (1) Development of E-Beam irradiation protocols for fruit salads, vegetable salads and cured meat dishes that can be used as part of a neutropenic diet for in-patient bone marrow and peripheral blood stem cell transplant recipients, (2) performing microbiological, nutritional and organoleptic characterization of the E-Beam irradiated dishes, (3) Conducting pilot-studies in selected hospitals to evaluate the effectiveness of neutropenic diets that contain E-Beam pasteurized foods in reducing infection rate and improving quality of life and nutritional status in immuno-compromised patients, (4) partnering with food service companies to delineate the commercial and technical issues surrounding the introduction of E-Beam irradiated foods into hospitals, and (5) developing educational and outreach materials related to food irradiation and E-Beam pasteurization that is targeted at the medical community including doctors, nurses, nutritionists, hospital food service providers, and hospital patients.

The project proposed will address the expected research outputs such as data on the microbiological and nutritional quality of irradiated foods, data on the acceptability of irradiated foods in hospitals, protocols for the manufacture of irradiated foods, and publication of research results. In the long term, the project will lead to better information surrounding the scientific and business issues pertaining to the introduction of irradiated foods into hospitals.

Food Research / Irradiated Food for Patients

Jayne Woodside, UK

Dr Woodside is a Reader in Clinical Biochemistry at Queen's University Belfast, with an interest in conducting whole foods and whole diet intervention studies with clinically relevant endpoints. She has a background in nutrition and epidemiology. Her presentation covered her background and interests, and also gave an overview of the use of and evidence supporting low bacterial diets in neutropenic patients.

Dr Woodside concluded that there was a need for clear guidelines/a consensus on the use of low bacterial diets, as current practice is inconsistent. She proposed a need for a worldwide survey, as the most recent survey of current practice was Europe-focused. She also concluded that the current evidence for the benefit of low bacterial diets was weak, and that there was a need for a systematic review of the literature, and further randomised controlled trials. Important questions in relation to irradiated foods include their cost effectiveness, palatability, and nutritional quality. Irradiated foods must be cost-effective, as this will be essential for acceptance by healthcare systems. The palatability of any new irradiated foods also needs to be tested, in a blinded way and in both healthy volunteers and patients. The nutritional quality of irradiated foods must also be confirmed, perhaps by the monitoring of nutritional biomarkers post-consumption of irradiated fruit and vegetables. Finally, an important question will be the views of patients on the need for irradiated foods. It would be possible to conduct focus groups with patients receiving low bacterial diets examining potential psychological impact and effect on quality of life.

The research outlined above would answer the CRP research outcomes in terms of providing information on the potential use of irradiated foods in immune-compromised patients, the nutritional and organoleptic properties of these foods, and on the acceptance of irradiated foods by hospitals and medical and dietetic professionals.

6. Conclusions and Recommendations of the First RCM

6.1 Conclusions

1. A common set of microbiological criteria / guidelines would facilitate the development and benchmarking of special foods for these target groups. There are no current guidelines (to the best of our knowledge) and food service practices in hospitals seem to vary between different hospitals and from country to country. Participants therefore decided to use research guidelines that contain microbiological criteria for foods intended for immuno-compromised patients and other target groups. This Research Protocol was developed during the meeting (Annex C).

2. The scope of work for a technical contract (survey) was discussed and participants agreed a number of issues that need to be addressed in order to support the CRP. These issues are:

- Current status of the use of clean diets and infection reduction
- Microbiological criteria (standards / guidelines / regulations)
- Countries that are using clean diets / sterile diets
- Microbiological criteria for special foods (non-hospital; e.g., astronauts, emergency rations)
- Information on well-being / psychological benefits of varied diet
- Hospital standards (cooked in-house / commercial supplier)
- Technologies and practices that are currently being used in different countries.
- Limitations / challenges of using clean diets

3. Educational material for healthcare professionals, patients and other stakeholders will be required to encourage adoption of the technology.

4. Irradiated foods developed under this CRP could have a place in regular hospital diets and in other situations where ensuring food safety is critical. It was concluded that targeting foods for in-patients would increase the probability of irradiated food being accepted by the medical community. Although functional foods, viruses and parasites are not yet included in the work plan, they may be considered in future.

5. Research findings from earlier CRPs can be used to facilitate and further develop irradiated foods for immuno-compromised patients and other potential target groups.

6.2 Recommendations

1. A web-user-group should be established that is dedicated to sharing information between participants. It is recommended that research protocols, educational material, communication media and relevant publications are placed on this web group and that it is established as early as possible. [Note that a web-group was subsequently established and is available to CRP participants[5]].

2. CRP participants should interact with their healthcare community to build a working relationship and encourage collaboration. Research should be guided by this collaboration to decide upon the target foods. Healthcare professionals and food suppliers should be encouraged to attend the next Research Coordination meeting. Communicating the benefits of irradiated food is critical to the successful adoption, development, marketing, and commercialization of irradiated foods for patients and other potential target groups. Research should be based on information from commercial food suppliers, as well as the healthcare and medical community, and relevant international organizations.

3. Foods developed under this research should also be suitable for commercialization. For example, irradiated foods could be developed for in-patients because these foods would have a good chance of being used by hospitals and therefore be of interest to commercial organizations that supply hospital food. The CRP should primarily concentrate on foods for immuno-compromised patients as well as other potential target groups.

4. Technical Cooperation projects should be sought to transfer this technology to other countries and disseminate information to decision makers on the value of irradiated foods for patients and other specific stakeholders (e.g. building technical capacity and exchange information by means of meetings or seminars involving regulatory and policy officials).

5. A template form for reporting research progress should be developed and circulated to participants to facilitate interim and final report preparation.

[5] https://groups.google.com/group/immunocompromised-foods-crp

7. Agreed Action Plan and Logical Framework

Action Plan (Activities)

Activity	2010	2011	2012	2013	2014 / 15
Announce CRP (early 2010). Receive proposals	X				
Evaluate proposals and select participants	X				
Award / renew Contracts and Agreements	X	X	X	X	X
Organize 1st RCM (Aug 2010) to establish network and develop overall CRP work plan, agree on specific foods, research protocols, governance, record keeping and reporting.	X				
Phase 1 Work Programme includes the awarding of a technical contract to undertake a survey; initial analyses / sensory testing of irradiated foods (produce microbiological & nutritional data and data on sensory tests), and writing draft research protocols.	X	X			
Organise 2 RCM (28 Nov – 2 Dec 2011 possibly Philippines) Review phase 1 and develop work plan for phase 2		X			
Phase 2 Work Programme includes further analyses / testing and production of data; establishing acceptability (to both medical professionals and patient target groups), and; finalising production protocols.			X	X	
Organise 3rd RCM (Jul 2013) to review work and develop work plan for phase 3. Prepare draft TECDOC and / or draft papers				X	
Phase 3 Work Programme includes sensory testing; reviewing data; gathering further data to address knowledge gaps, and; publishing production protocols online.				X	X
Organise Final RCM (Nov 2014) to review work and prepare final TECDOC and research papers					X
Produce TECDOC					X/X

Logical Framework

	Project Design Elements	Verifiable Indicators	Means of Verification	Important Assumptions
Overall Objective:	Increase the variety, availability and acceptability of foods for immuno-compromised hospital patients and other target groups.	A range of irradiated foods developed for immuno-compromised patients	Reports provided at RCMs, published in scientific and medical literature and the TECDOC	Hospitals work in collaboration with participating partners
	Generate data on the acceptability of irradiated foods for patients	(i) Quantitative data on microbiological safety, nutritional and organoleptic properties. (ii) Qualitative data on psychological well-being and quality of life	Written reports and published scientific papers	Hospital patients participate in study (required for qualitative assessments)
Specific Objective:	To research and develop a range of simple and complex irradiated foods for immuno-compromised patients and potentially other target groups	Production of irradiated foods for patients i.e. fresh produce (fruits vegetables, salads) ready to eat meals (ethnic or locally produced) and functional foods	(i) Production protocols for the manufacture of irradiated foods for patients. (ii) Microbiological, nutritional & organoleptic criteria for irradiated foods (iii) Data on the use of irradiation in combination with other food technologies	Continued commitment by all participants
Outcomes:	The medical community, immuno-compromised hospital patients and other target groups have access to irradiated foods	Irradiation facilities producing food for the immuno-compromised and other target groups	Inclusion in national regulations; Reports from National authorities for inclusion in FAO / IAEA Food Irradiation Facilities Database	There is interest and up-take by commercial scale irradiation facilities
	Microbiological, nutritional and organoleptic criteria for irradiated foods	Criteria are produced	Criteria are published	There is consensus on a common set of criteria
	Increased knowledge on the acceptance of irradiated foods by patients and specific target groups	Increased number of scientific articles and papers	Literature search and citation index	Medical community is aware of irradiation studies
	Increased acceptance of irradiated foods by hospitals, medical professionals and	Increased interest in irradiated foods for patients	Level of enquiries from Member States and healthcare professionals.	Records of enquiries are maintained

	other potential target groups		(ii) Generation of TC projects	
	Protocols for the manufacture of irradiated foods for patients	Production of protocols	Protocols published and disseminated	A limited number of protocols can be produced to cover a broad range of different foods
	Increased trade in irradiated food products for patients and other target groups	Irradiated foods are produced commercially	Trade data	Trade data are collected and made available

Outputs:	Data	Data on (i) the microbiological safety, nutritional and organoleptic properties, including the acceptability of irradiated foods for patients (ii) the use of irradiation in combination with other food technologies	RCM reports and publication of data in scientific literature	Journals accept submitted material for publication
	Products	Production of irradiated foods for patients and other target groups i.e. fresh produce (fruits vegetables, salads) ready to eat meals (ethnic or locally produced) and functional foods	Availability of irradiated products	Technology is accepted by patients, hospitals and commercial sector.
	Protocols	Production of protocols for the manufacture of irradiated foods for hospital patients and other target groups	Publication of protocols / guidelines on internet	A limited number of protocols can be produced to cover a broad range of different foods
	Publications	Production and dissemination of technical documents, research papers and educational / communication material.	(i) Published papers on the applicability of food irradiation for patients diets. (ii) RCM reports, (iii) technical document (iv) educational / communication material	Continued support and participation of CRP institutions. Participants submit research findings for publication

Activities:	Consultants Meeting	Scope of work developed, range of foods considered and a priority list produced, potential participants discussed	Report of Consultants Meeting	Consultants available to meet
	Research Contract & Agreement Holders	Research Contract & Agreement Holders	Agreement / research contracts signed	Applications forthcoming from a

	identified and recruited	recruited		range of potential participants
	1st RCM Meeting (Aug 2010)	Establish network and develop work programme, agree on specific food items for study; research protocols; governance; record keeping; reporting	First RCM report	Participants can attend meeting
	Review Research Contract and Agreement holders	Award / renew contracts	Agreement / research contracts signed	Continued commitment by institutions and participants
	2nd RCM (28 Nov – 2 Dec 2011)	Review progress of work plan. Consider phase 2 workplan and prioritise tasks for phase 2	2nd RCM report and scientific papers	Continued commitment by institutions and participants
	Review Research Contract and Agreement holders	Award / renew contracts	Agreement / research contracts signed	Continued commitment by participant
	3rd RCM (Jul 2013)	Review progress of work plan. Consider final phase of work, prepare TECDOC and research papers for publication	3rd RCM report and scientific papers	Continued commitment by institutions and participants
	Review Research Contract and Agreement holders	Award / renew contracts	Agreement / research contracts signed	Continued commitment by institutions and participants
	4th RCM (Nov 2014)	Review work and prepare TECDOC	TECDOC, Scientific papers	Commitment by institutions and participants

Annex A

List of Participants

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Annex B

Agenda

1st RCM of the CRP on the Development of Irradiated Foods for Immuno-Compromised Patients and other Potential Target Groups

23 – 27 August 2010
IAEA Vienna, Austria
Room A0742

Scientific secretary: Carl Blackburn c.blackburn@iaea.org
Administrative secretary: Stella Attakpah s.attakpah@iaea.org

Day 1: Monday, 23 August 2010		
08:00	Registration (UN Pass Office, Gate 1)	All
09:00	Welcome & Opening Address	Qu Liang, IAEA
09:15	Introductions & Background of Participants	David Byron, IAEA, All
09:35	Election of Chairperson	David Byron, IAEA
09:40	Adoption of Agenda	Chairman
09:50	Meeting Objectives	Carl Blackburn, IAEA
10:00	CRP Background	Carl Blackburn, IAEA
10.30	***Break***	
11:00	Food & Environment Protection Section, Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture	David Byron, IAEA
11:20	Nutrition and Health-Related Environmental Studies Section, IAEA Division of Human Health	Christine Slater, IAEA
11:40	Research Contracts Administration and CRPs	Bashur Bashur, IAEA
12:00-13:30	***Lunch / Administrative Arrangements***	
Session 1: Presentations – Research Contracts **(Proposed research work plan, summary of work to date and meeting the objectives of the CRP)**		
13:30	Conclusions and Recommendations from the Consultants Meeting of 24 – 27 November 2009	Carl Blackburn - IAEA
14:00	Widening the Meals Variety for Immunocompromised Persons and Other Target Groups by Ionizing Radiation	Maria Constanza Cova Argentina
14:45	Use of Irradiation for Shelf Stable Sterile Foods for Immunocompromised Patients and Other Specific Groups	Mohammad Alam Bangladesh
15:30	***Break***	
16:00	Application of Ionizing Radiation: Foods for People with Specific Diets	Susy Frey Sabato Brazil
16:45	Use of Irradiation for Low Salt Chinese Traditional Pickles for Immunocompromised Patients	Gao Meixu China
17:30	***End of day 1***	

Day 2: Tuesday, 24 August 2010		
Session 1 (Continued): Presentations – Research Contracts **(Proposed research work plan, summary of work to date and meeting the objectives of the CRP)**		
09:00	Use of Irradiation to Provide a Wider Selection of Safe, Nutritionally and Organoleptically Adequate Foods for Immuno-Compromised Patients	Csilla Mohacsi-Farkas Hungary
09:45	Irradiated Foods For Immunocompromised Patients And Other Potential Target Groups In India	Arun Kumar Sharma India
10:30	***Break***	
11:00	Development of Safe Ethnic Foods - Irradiation for Specific Target Groups Including Immunocompromised Patients	Zubaidah Irawati Koenari Indonesia
11:45	Selection of Irradiation Doses and Packaging Materials to Enhance Market Life of Sterile and Hygienic Meals for Patients and Other Specific Communal Groups	Anwar Ahmad Pakistan
12:30	***Lunch***	
13:30	Development of Safe, Quality and Shelf-Stable Filipino Ethnic Foods for Immunocompromised Patients and Calamity Victims	Zenaida De Guzman Philippines
14:15	Combination Treatments Involving Irradiation in Order to Develop Shelf Stable Sterile Foods for Immunocompromised Patients and Other Specific Target Groups	Samia Ayari Tunisia
15:00	***Break***	
Session 2: Presentations from Agreement Holders		
15:30	Irradiation for Shelf Stable Sterile Foods for Immunocompromised Patients and Other Specific Target Groups	Ju-Woon Lee Republic of Korea
16:15	E-Beam irradiated diets for neutropenic bone marrow transplant recipients: technology and hospital food supply chain considerations.	Suresh Pillai USA
17:00	***End of Day 2***	

Day 3: Wednesday, 25 August 2010		
Session 2 (Continued): Presentations from Agreement Holders		
09:00	Food Research / Irradiated Food for Patients	Jayne Woodside UK
Session 3: Discussion and elaboration of written presentation summaries and CRP framework		
09:45	Writing session – participants to produce a written summary of their presentation and include a short description of how their research will contribute to achieving the CRP objectives	Individual writing
10:30	***Break***	
11:00	Presentation and review of summaries	All
11:45	Discussion / re-examination of CRP Framework	All
12:30	***Lunch***	
Session 4: Discussion and elaboration of protocols and guidelines		
13:30	Discussion of: - Research protocol / guidelines to ensure consistency (a) The application and reporting of dosimetry (b) Microbiological criteria / definition of efficacy (c) Ethical reviews (food trials on patients) (d) Other? • Quality assurance • Production protocols • Record keeping • Reporting	All
15:00	***Break***	
15:30	Discussion and drafting of research protocol and guidelines	All
17:00	***End of Day 3***	
17:30	***Reception***	**All**

Day 4: Thursday, 26 August 2010		
Session 4 (Continued): Discussion and elaboration of protocols and guidelines		
09:00	Finalization of guidelines on the application and reporting of dosimetry to ensure consistency	All
09:45	Finalization of common / standard research protocols	All
10:30	***Break***	
Session 5: Preparation of final draft report		
11:00	Discussion of Technical Contract (Survey)	All
12:00	***Lunch***	
13:00	Elaboration and finalization of conclusions and recommendations (draft conclusions and recommendations to meet the CRP objectives)	All
15:00	***Break***	
15:30	Preparation of draft meeting report	All
17:30	***End of day 4***	

Day 5: Friday, 27 August 2010		
Session 6: Finalization and adoption of report		
09:00	Discussion and finalization of final draft meeting report	All
10:30	***Break***	
11:00	Identifying project strengths, weaknesses and opportunities	All
12:30	***Lunch***	
13:30	Presentation, discussion and adoption of final meeting report, including conclusions and recommendations	All
15:15	Closing remarks and end of meeting	All

Annex C

RESEARCH PROTOCOL

It is important to involve health professionals in the design of the experiment. The participants are looking forward to the survey results that will provide information on the current practices and microbiological criteria of hospital foods and other target groups.

1. Materials

1.1. Food
The types of food studied should be chosen in consultation with local healthcare professionals. The experiments should be carried out on foods that are representative of good quality food and from a reliable source.

Cooked ready to eat meals must be prepared according to a standard recipe so it can be prepared to the same standard repeatedly or ready to eat meals should be bought from a standard food service provider. It is important that the food does not vary to ensure consistency of the product following irradiation.

1. 2 Packaging
Packaging material should be suitable for use in radiation processing. It is necessary to demonstrate that the packaging retains its integrity over the usable life of the food product. The packaged food should meet the requirements of the target group (e.g. hospital kitchen) and be suitable at the target irradiation dose.

1.3 Reagents
Standard chemicals and media should be used in the research

2. Methods

2.1 Microbiological Experiments
Studies involving the inoculation of food should take care to ensure that the organisms are either deposited in a culture collection or preserved for future reference. All experimental protocols should be recorded.

Inoculation should involve products in their "normal" (non-irradiated / non-sterile) state.

2.2 Physical, Chemical, nutritional and Sensory Analysis
Analyses should be designed to provide data that is relevant to the experimental objectives

2.3 Record Keeping
Methods employed to produce the food should be documented (e.g. packaging temperature, atmosphere, storage temperature, irradiation conditions etc.)

3. Dosimetry

The dosimetry system should be calibrated and dose should be traceable to an international standard. Dosimetry should be employed according to recognized international standards. The minimum and maximum doses absorbed by the irradiated product should be determined, striving for dose uniformity. Routine dosimetry should be conducted, and a dosimetry report should be provided for each experiment.

International Standards and other guides are available to assist with conducting dosimetry for research on food and agricultural products, including:

> ISO/ASTM 51261 Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing.

ISO/ASTM 51900 Standard Guide for Dosimetry in Radiation Research on Food and Agricultural Products.

The key parameters required for dosimetry and reporting dosimetry include the following:

1. Calibration of radiation field inside the product box with confidence interval and traceability to a recognized national standard.

2. A statement or reference to details of the dosimetry system employed.

3. Uncertainty / confidence interval on the dosimetry system.

4. Dose mapping exercise for each configuration used (D_{max}, D_{min}, and dose distribution). The loading pattern for dose mapping should be recorded (a diagram for example).

5. The loading pattern for subsequent treatments should be the same as that used in the dose mapping exercise and should be recorded with reference to the dose mapping exercise.

6. The location for the placement of routine dosimeter(s) and the relationship between the dose received by dosimeter(s) at the routine location and the D_{max} and D_{min} (obtained from dose mapping).

7. The type of radiation and the source used should be recorded. Information related to irradiation treatment should include
i. Source strength.
ii. Radiation type

8. The following information should also be recorded:
- Target dose.
- Measured dose (and confidence interval).
- Dose rate.
- Dose uniformity ratio.
- A statement on how the dose was delivered, for example, was the dose delivered in a single treatment or by multiple exposures.

4. Microbiological criteria

There is an absence of commonly agreed microbiological criteria and the meeting decided to develop criteria that could be used by CRP participants. The following are sanitary microbiological levels suggested for foods intended for immuno-compromised people and other potential target groups. These criteria have been derived from Brazilian guidelines, the International Commission on Microbiological Specifications for Foods (ICMSF)[6] , information in a scientific paper by Pizzo et al [7], European Regulations on food hygiene and criteria recommended by Ju-Woon Lee that were certificated for use in space flight conditions by the Russian Institute for Biomedical Problems. Participants are strongly urged to follow the Bacteriological Analytical Manual (BAM) for Microbiological Analyses and Data reporting[8].

Aerobic Plate Counts < 500 cfu/g

Listeria spp not detected in 25 g

Salmonella spp not detected in 25 g

[6] www.icmsf.org

[7] Pizzo PA, Purvis DS, Waters C. Microbiological evaluation of food items for patients undergoing gastrointestinal decontamination and protected isolation. J. Am. Diet. Assoc. 1982 Sep;81 (3): 272-9

[8] www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm

Yeast and Mould < 10 cfu / g

Total Coliforms < 10 cfu / g

Staphylococcus aureus < 10 cfu / g

Aerobic spore count < 10 cfu / g

Anaerobic spore count < 10 cfu /g

5. Quality Assurance / Good Laboratory Practice

Statistical advice should be sought prior to experimental design and during data analysis.

Data sheets, survey forms and similar documents should be archived so that they can be made available for future reference. All original data should be retained so it can be made available in future.

Records should include details and descriptions of

- The food and preparation recipes
- Packaging material
- Food bioburden prior to irradiation (this should be determined and recorded)
- Inoculation studies (record the organism details and description).
- Conditions of irradiation (see dosimetry)

An active web-site will be used to facilitate information sharing and will be open to CRP members and others involved in the research project.

6 Clinical Studies

Nutritional advice should be sought wherever appropriate. Studies should be carried out in collaboration with a medical professional, if patients are involved, and appropriate local governance guidelines should be followed (e.g. including ethical approval).

7. Educational Material

Written documents and presentations will be prepared and developed. Information will be shared on the internet forum (Google immunocompromised foods)

Annex D

Table 1 Foods Represented in CRP to Develop Irradiated Foods for Immuno-Compromised Patient and Other Potential Target Groups

Country	Food(s)	Target Group	Safety and quality parameters			
			Nutrition	Micro-biological safety	Shelf life extension	Sensory
Argentina	Fruit and veg, stuffed products (meat, veg, cheese),	Hospital	X	X	X	X
Bangladesh	Fresh veg,	Hospital	X	X	X	X
Brazil	Fruits, veg, ice-cream	Hospital	X	X	?	X
China	Pickles (veg)	Hospital	X	X	X	X
Hungary	Fruits, veg	Hospital	X	X	?	X
India	To be decided in consultation with hosp	Hospital	X	X	X	X
Indonesia	Prepared meals (Fish, meat, chicken), plus fruit and veg.	Hospital and different target groups (rations).	X	X	X	X
Pakistan	Prepared meals (legumes and chicken) plus herbal bread and herbal ice-cream.	Hospital Calamity victims	X	X	X	X
Philippines	Meat products, (Pork Adobo) (PHI Beefsteak)	Hospital Calamity victims	X	X	X	X
Tunisia	Veg, red meat	Hospital	?	X	X	X
Republic of Korea	Veg, fruit, prepared meal (chicken and rice cake). Ice cream, porridge, kimchi.	Hospital Emergency rations Astronauts	X	X	X	X
USA	Fruit salads, veg salads, dried meat dishes (beef).	Hospital	X	X	?	X