Use of ionising radiation : report of the House of Representatives Standing Committee on Environment, Recreation, and the Arts.

AUSTRALIA

Use of Ionising Radiation

Report of the House of Representatives Standing Committee on Environment, Recreation and the Arts

November 1988

THE PARLIAMENT OF THE COMMMONWEALTH OF AUSTRALIA

USE OF IONISING RADIATION

Report of the House of Representatives
Standing Committee on Environment, Recreation and the Arts

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TERMS OF REFERENCE

That the Committee inquire into and report on the use of ionising radiation for commercial sterilisation, disinfestation, food preservation and other purposes with particular reference to:

- human health and safety;
- environmental impacts, and
- adequacy of assessment and regulatory procedures.

ABBREVIATIONS

ACA	Australian Consumers' Association
AEC	Atomic Energy Commission (US)
AECL	Atomic Energy of Canada Limited
ANSTO	Australian Nuclear Science and Technology Organisation
BP	benzopyrene
Burgen	Advisory Committee on Irradiated and Novel Foods (UK)
CAST	Council for Agricultural Science and Technology (US)
CCFI	Citizens Concerned about Food Irradiation
CNFF	Campaign for Nuclear Free Food
COD	Committee of Direction of Fruit Marketing (Qld)
Codex	Codex Alimentarius Commission
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAA	Dietitians Association of Australia
DNA	deoxyribonucleic acid
DOE	Department of Energy (US)
EB	electron beam
EDB	ethylene dibromide
EEC	European Economic Community
EPHCP	Environment, Public Health and Consumer Protection Committee (European Parliament)
ESR	electron spin resonance
FAO	Food and Agriculture Organization (Joint)
FDA	Food and Drug Administration (US)
FSC	Food Standards Committee (NH&MRC)
FST	Food Science and Technology Subcommittee (NH&MRC)
GATT	General Agreement on Tariffs and Trade
GBq	gigabecquerel
IAEA	International Atomic Energy Agency
IBT	Industrial Biotest Laboratories (US)
ICRP	International Commission on Radiological Protection
IFIP	International Food Irradiation Project
JECFI	Joint Expert Committee on Food Irradiation (FAO/IAEA/WHO)
kGy	kilogray
MB	methyl bromide
NH&MRC	National Health and Medical Research Council
NIN	National Institute of Nutrition (India)
PHAC	Public Health Advisory Committee (NH&MRC)
RDA	recommended daily allowances
US	United States (of America)
USDA	United States Department of Agriculture
WHO	World Health Organization

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RECOMMENDATIONS

The Committee recommends that:

1. the Minister for Community Services and Health, in consultation with State and Territory health Ministers, request the National Health and Medical Research Council to introduce administrative procedures enabling fuller public consultation and participation in the development of food standards regulations.
(paragraph 4.104)

2. the Australian Government request the World Health Organization to:
   - review existing data relating to the safety of irradiated food;
   - produce a fully referenced report on the safety of food irradiation, and
   - identify those areas where further research is required.

(paragraph 5.143)

3. (i) the Australian Government request the World Health Organization to review all existing data relating to the impact of food irradiation on nutrients to identify areas where data is adequate and areas where more research is required, and
   (ii) produce a fully referenced report on the impact of food irradiation on nutrients, with particular reference to
   - the impact on human health.

(paragraph 6.36)

4. if the irradiation of food were to be approved the Minister for Community Services and Health request Commonwealth and State Public Health Authorities to monitor the quantities and types of foods which are irradiated.
(paragraph 6.38)

5. if the irradiation of food were to be approved the Minister for Community Services and Health ensure that all future dietary intake surveys are designed in a manner which would enable identification of those at risk groups who may consume irradiated food as a significant proportion of their diet and whose diet may be nutritionally inadequate.
(paragraph 6.39)

6. the Minister for Community Services and Health request State Ministers to require that plant supervisory staff have radiation safety training at a level appropriate to their degree of supervision to include:
   - some understanding of radiation physics;
   - biological effects of radiation;

. radiation units;
. control and emergency procedures, and
. plant safety design.
(paragraph 7.26)

7. the Minister for Community Services and Health request State Ministers to require plant operators be given radiation safety training to include:
. the effects of radiation;
. operation and use of radiation monitors;
. exposure limits, and
. plant safety and emergency procedures.
(paragraph 7.27)

8. the Minister for Industry, Technology and Commerce request the Australian Nuclear Science and Technology Organisation to develop suitably equipped radiation safety specialists and engineers to provide assistance in the event of any unusual occurrences at Australian and regional irradiation facilities.
(paragraph 7.51)

9. the Minister for Community Services and Health request the State Ministers to require that each irradiation plant hold an emergency exercise at least every two years to test the response of plant personnel and equipment.
(paragraph 7.58)

10. the Minister for Industry, Technology and Commerce require that the Australian Nuclear Science and Technology Organisation ensure that as a condition for the import of cobalt 60 sources the suppliers be required by contract to accept the return of expired sources.
(paragraph 7.67)

11. the Minister for Industry, Technology and Commerce prohibit the import of caesium 137 for use as an irradiation source in commercial irradiation facilities.
(paragraph 7.79)

12. the Minister for Industry, Technology and Commerce prohibit the import of radioactive isotopes for use as an irradiation source in mobile commercial irradiation facilities until suitable operating techniques have been developed and problems relating to regulation and safety have been resolved.
(paragraph 7.82)

13. the Minister for Community Services and Health discuss with State and Territory health Ministers the prohibition of the use of electron beam or x-ray machines for use in mobile commercial irradiation facilities until suitable operating techniques have been developed and problems relating to regulation and safety have been resolved.
(paragraph 7.83)

14. (i) the Minister for Industry, Technology and Commerce direct the Australian Nuclear Science and Technology Organisation to ensure that before approval is granted to import radioactive sources proposed irradiation facilities be subject to an Environmental Impact Assessment which satisfies the conditions of the Environment Protection (Impact of Proposals) Act 1974 and includes an assessment of the maximum credible accident, and

(ii) detailed certificates of competence of plant operators be submitted and assessed.

(paragraph 7.91)

15. the Attorney-General require that standard insurance contracts be worded in such a manner as to make it clear that the policy covers damage from gamma sterilisation plants and the transport of radioactive isotopes to and from those plants.

(paragraph 7.96)

16. the Australian Government should not approve the irradiation of food in Australia until such time as a routine commercial method of detection has been developed.

(paragraph 8.8)

17. the Minister for Community Services and Health request the National Health and Medical Research Council to redraft the Model Food Standards Regulations, Section 3, Irradiation of Food, to include a specified list of food products (not classes of foods) which may be irradiated, and these foods be included in a schedule to the regulations stipulating the purpose for which irradiation has been approved and the minimum and maximum absorbed dose approved to achieve that effect.

(paragraph 8.17)

18. the regulations require that submissions to the National Health and Medical Research Council seeking approval to irradiate a food include:
    - details of the purpose;
    - minimum and maximum dose;
    - data on nutritional effects;
    - data on chemical, physical or microbiological changes;
    - conditions of storage and handling, and
    - details of packaging, and any other processes to be applied to the food prior to or after irradiation.

(paragraph 8.18)

19. (i) food irradiation regulations be formulated to require that food be labelled in accordance with clause 9(a) of the National Health and Medical Research Council Model Food Standards Regulations, Section 3, Irradiation of Food, and

(ii) the regulations stipulate that individual items, if sold loose, be individually labelled or stamped as irradiated.
(paragraph 8.23)

20. the food irradiation regulations specify -
    . the packaging material which may be used during the irradiation of pre-packed foods;
    . the type of food for which each packaging material may be used, and
    . the maximum dose permitted for each type of packaging material.
    (paragraph 8.28)

21. the food irradiation regulations specify -
    . individual foods which may be re-irradiated;
    . the circumstances in which those foods may be re-irradiated, and
    . the maximum total accumulative dose approved.
    (paragraph 8.33)

22. the Minister for Community Services and Health request State Ministers to ensure that before the commencement of operations, in the case of a new plant, and after the loading of fresh sources or other modifications in an existing plant, any company carrying out food irradiation provide State regulatory authorities with:
    . details of radiation field strength and dose contours;
    . details of proposed radiation times for the different foods to be irradiated, and
    . details of dose controls to be used, such as type of dosimeter.
    (paragraph 8.42)

23. food irradiation regulations be drafted to require extensive records to be kept in accordance with the National Health and Medical Research Council Model Food Standards Regulations, Section 3, Irradiation of Food, clauses 8 and 10.
    (paragraph 8.52)

24. food irradiation regulations include specific provisions to enable public health authorities free access to irradiation facilities and their records.
    (paragraph 8.53)

25. food irradiation regulations contain penalties sufficiently severe to ensure compliance.
    (paragraph 8.55)

1. INTRODUCTION

Background

1.1 Over recent years food irradiation has become a major issue of concern to many Australians. These concerns are increasingly being expressed to Government and other relevant bodies through representative organisations or by individuals. Many petitions, containing thousands of signatures, have been presented to Parliament.

1.2 As a consequence of this interest the former House of Representatives Standing Committee on Environment and Conservation, in September 1986, resolved to inquire into the use of ionising radiation as it relates to commercial sterilisation, disinfestation and food preservation, with particular reference to human health and safety, environmental impacts and the adequacy of assessment and regulatory procedures. The main emphasis of the inquiry was on food irradiation.

1.3 While many individuals and organisations are concerned about the introduction of food irradiation it is clear that some regulatory authorities, scientific organisations and commercial associations, particularly the horticulture industry, consider that food irradiation is safe and can bring distinct advantages to industry and to the consumer. While food irradiation is not used extensively worldwide, 30 countries have given approval to the irradiation of some food products.

1.4 In August 1986 the Minister for Health referred the issue of food irradiation to the Australian Consumers' Association (ACA) for investigation and report. ACA presented its report in May 1987. The Environment and Conservation Committee saw its inquiry as complementary to ACA's but with wider ranging terms of reference, more extensive powers to call for information and the advantage of the protection of Parliamentary privilege to witnesses.

Conduct of the Inquiry

1.5 The Committee commenced its proceedings by meeting with the ACA to discuss relevant issues and procedures and by inspecting the Australian Nuclear Science and Technology Organisation (ANSTO) facility at Lucas Heights and the Ansell Steritech plant at Wetherill Park to gain an insight into their operations and the complex scientific issues involved.

1.6 Public hearings commenced in March 1987 and representatives of the Federal and State Governments, industry, consumer and conservation organisations, experts in the various relevant fields and individuals participated in well attended and widely reported meetings in Sydney, Melbourne, Brisbane, Adelaide and Canberra. The Committee's program was curtailed from June to September as a result of the General Election in July.

1.7 On 24 September 1987 the Standing Committee on Environment, Recreation and the Arts was appointed and in December the reference, in identical terms to that of the former Committee, was received from the Minister for Consumer Affairs and accepted by the Committee for inquiry. In February 1988 the Committee appointed a sub-committee of 5 members to undertake the program of hearings. The members appointed to the sub-committee were all members of the former Committee and involved with the inquiry since its inception. Three specialist advisers were also appointed by the Committee to provide expertise to the inquiry.

1.8 Further public hearings were conducted in Sydney, Melbourne, Perth, Hobart and Canberra and concluded in September 1988.

1.9 Throughout the inquiry a large number of documents were received by the Committee from proponents and opponents of the process, together with many reports and articles on studies and inquiries conducted overseas.

1.10 In the 34th and 35th Parliaments the Committee and the sub-committee conducted 20 public hearings with 4000 pages of transcript taken from 134 witnesses. Hundreds of other written submissions, letters and telephone calls were received, which although supplementary to the oral evidence were nevertheless as important and of equal value when the Committee was preparing and discussing its report.

Issues of Concern

1.11 Throughout the inquiry a number of concerns were expressed to the Committee regarding the effects of irradiation and the possible unknowns relating to it. The Member for Hindmarsh submitted a list of concerns contained in over two thousand letters. The ACA inquiry categorised these concerns as health, environmental and economic. The ACA assessment is reproduced below and reflect the concerns expressed to the Committee's inquiry.

(i) Health of the Consumer

- There have been instances of assurances of safety of substances which have proved, in hindsight, to have been false;
- The research on the safety of irradiated food has yielded some conflicting results and conclusions;
- The substances formed within food by irradiation (radiolytic substances) may be toxic;
- Fears that food will become radioactive;
- Fears that food will become "dead" following irradiation;

. The possibility that irradiation will be used to clean up food which is unacceptably contaminated;

. Aflatoxin producing moulds may thrive in irradiated food;

. Botulism causing bacteria may go undetected in irradiated foods;

. Nutrients, especially vitamins, are reduced by irradiation.

(ii) Environmental

. Accidents may occur while cobalt 60 or caesium 137 is being transported;

. If cobalt 60 becomes scarce or expensive it may be replaced with the less acceptable more dangerous caesium 137;

. Accidents can happen in facilities resulting in:

- leakage of radioactive water;

- some of the isotope source coming out of the source chamber onto the conveyor;

. Fires, floods or earthquakes could damage a facility;

. Australia could be required to dispose of partly spent cobalt or caesium;

. Lack of regulations and controls over the siting and operation of irradiation facilities;

. Lack of uniformity in State legislation;

. Irradiation resistant micro-organisms could be bred.

(iii) Economic

. There may be initial subsidising of the industry either directly (as in Japan) or indirectly by governments meeting costs of community education and regulation with the true cost being passed on to consumers regardless of whether they eat irradiated food or not;

. There may be an ultimate cost to the consumer while a highly expensive centralised process squeezes out the small primary producer or small business;

. The primary economic gain going to large companies.

(iv) Additional Concerns

. Deleterious effects of taste, smell and texture of irradiated food;

. Unnecessary processing of food;

. Concerns relating to blanket approval of up to 10 kGy rather than item by item approval.

. The probability that labelling regulations will not be enforced and therefore the consumer will not have a choice;

. Imported irradiated food coming from countries where there is a lack of adequate controls;

- Due to lack of dose uniformity, especially in large boxes, some food will receive excessive doses;

- The lack of a test to determine whether food has been irradiated;

- The possibility that food could be re-irradiated;

- The right to purchase food which is fresh and unprocessed;

- Selling irradiated food to developing countries when simpler technologies to overcome famine and malnutrition would be more appropriate.

1.12 The Committee realises that some adverse comments may reflect a lack of knowledge of some aspects of food irradiation and that perhaps with more information some people might have been less concerned. However these comments indicate that people demand the right to be informed and consulted about a process which could have significant effects on the food they eat.

Acknowledgements

1.13 The Committee acknowledges the co-operation and assistance from all who submitted submissions, assisted with inspections and gave oral evidence to the Committee over the course of the inquiry. The Committee wishes to make special mention of the Australian Nuclear Science and Technology Organisation and Ansell Steritech for the opportunities to inspect their facilities and for their willingness to provide any information requested of them.

1.14 Although a large amount of the evidence was taken by the Standing Committee on Environment and Conservation in the 34th Parliament, the conclusions and recommendations are those of the

present Standing Committee on Environment, Recreation and the Arts. The Committee appreciates the contribution made to the inquiry by the members of the previous Committee.

1.15 Mr Dobie advised the Committee that he was not in a position to agree or disagree with the Committee's conclusions and recommendations. Mr Dobie was unable to participate in the Committee's inquiry and therefore believed that it was inappropriate for him to be associated with a report which required detailed knowledge of highly technical matters.

1.16 The Committee wishes to record its special thanks to the three advisers, Dr Wayne Hall, Dr Don MacPhee and Mr Rob Robotham, for the invaluable time, effort and expert knowledge they provided to the inquiry.

2. USE OF IONISING RADIATION

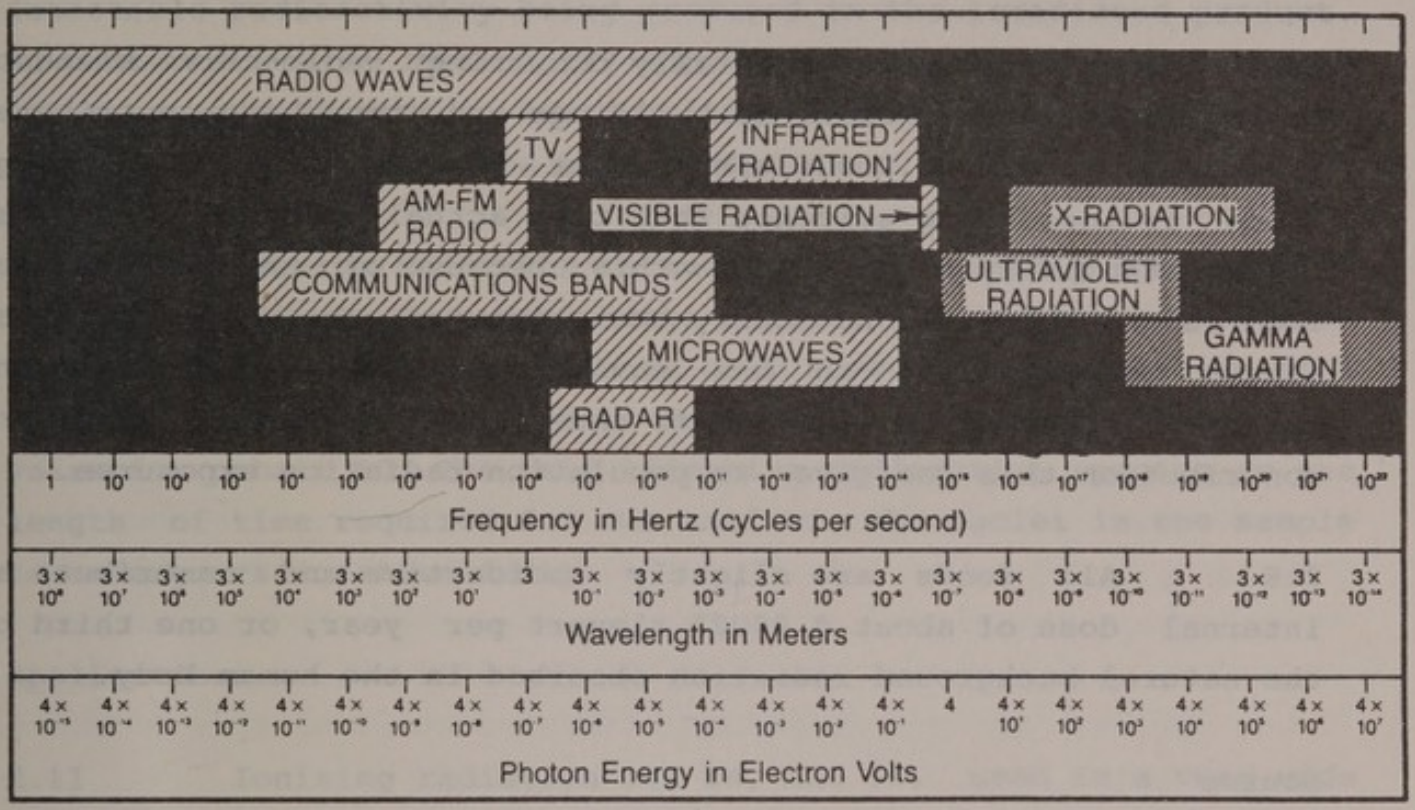
Ionising Energy

2.1 As defined by the United States Council for Agricultural Science and Technology (CAST), electromagnetic radiation is a form of energy that moves through space at the speed of light with simultaneous variation of the electric and magnetic fields and occurs in a wide range of wavelengths (see Table 1). The various regions of the spectrum range from radio waves (the longest wavelength) through television, radar, microwave and infrared radiation to light waves in the visible range (which have short wavelengths). From light waves the spectrum continues through ultraviolet radiation, x-radiation and gamma radiation (the very short wavelengths).

2.2 When the quantity of energy in the radiation wave exceeds the energy that binds adjacent atoms in a molecule, the absorption of this energy by the molecule can break the chemical bond and cleave the molecule into smaller fragments which may be either electrically charged (ions) or neutral (free radicals). Visible light can break only the weakest bonds. Ultraviolet radiation is able to break somewhat stronger bonds. X and gamma radiations carry sufficient energy to be able to expel orbiting electrons from the atoms being irradiated. These ejected electrons are called negative ions and the types of radiation that can produce this effect are known as ionising radiation or ionising energy. Gamma rays are an important ionising radiation, because of their short wavelength they can be very penetrating.

TABLE 1

THE ELECTROMAGNETIC SPECTRUM



The frequencies, wavelengths, and photon energies of the major part of the electromagnetic spectrum. The boundaries of the named segments are more or less arbitrary, and there is now some tendency to reduce the overlapping by defining the range between TV and infrared radiation as microwaves and the range between visible radiation and x-radiation as ultraviolet.

Source: Council for Agricultural Science and Technology

Natural Background Radiation

2.3 In their normal environments, humans are exposed continuously to radiation from the stars and the sun and to radiation produced when atoms of naturally occurring radioactive elements in the body and the environment decay with release of ionising energy. The dose of ionising energy absorbed by humans is measured in units known as sieverts. The sievert measures the amount of energy deposited in human tissues and includes a factor allowing for the different biological effects produced by different types of radiation. It is known as the unit of dose equivalent.

2.4 Cosmic radiation, received from outer space, contributes to the human body a radiation dose of about 0.00028 sievert per year on the average at sea level, increasing with altitude.

2.5 Radiation from naturally occurring radioactive elements in the soils, rocks, walls of buildings and atmosphere contributes a dose of about 0.00026 sievert per year on average, although there is increasing evidence that the actual exposure levels may be substantially higher than this, because of the contribution from radon. This is a naturally occurring radioactive gas that has always been present in the environment. Improved measurement techniques have lead to a better understanding of the significant contribution this gas gives to population radiation exposures.

2.6 All foods are slightly radioactive and contribute an internal dose of about 0.00027 sievert per year, or one third of the natural background radiation absorbed in the human body.

Source

2.7 The process whereby unstable nuclei emit ionising radiations is called radioactivity. Radioactive materials occur naturally or can be made artificially. Uranium is an example of a naturally occurring radioisotope. Cobalt 60 is artificially produced in a nuclear reactor by bombarding cobalt 59 with neutrons. Another gamma emitter is caesium 137 which is also formed in a nuclear reactor from the splitting (fission) of uranium - it can be extracted as a by-product of the reprocessing of used reactor fuel elements.

2.8 Radioactivity cannot be switched off nor can the decay process be speeded up. Electron beam (EB) machines can produce x-rays of great intensity in a manner very similar to medical x-ray units. Such machines can be switched on and off.

2.9 For irradiation purposes cobalt 60 is the radioisotope of choice. Cobalt sources are at present readily available, convenient to use, the technology for production, fabrication and encapsulation is highly developed and there is no chance of detectable radioactivity being produced in the irradiated product. An alternative is caesium 137 which is in relatively small supply as a commercial source, however large amounts of nuclear reactor waste exist which could be reprocessed.

2.10 Caesium radiation is much less penetrating than cobalt, is more difficult to process into usable sources and is therefore less commercially attractive. It has, however, the advantage of a longer half life. Thirty years for caesium 137, as opposed to 5.3 years for cobalt 60. The half life of a radioactive species is the length of time required for one half of the nuclei in the sample to undergo radioactive decay.

Applications

2.11 Ionising radiation can be, and is, used in a very wide range of applications. Medical applications include the use of x-ray and injected radioisotopes to produce images of bones and other organs, to therapy machines used to control cancer.

2.12 Some industrial applications, such as smoke detectors, use very small amounts of radioactive material. Others, such as thickness gauges used for radiographing welds and pipes, can use quite large sources.

2.13 Major uses of ionising radiation are for sterilisation, preservation and disinfestation.

2.14 Sterilisation involves the highest level of microbial control and requires the largest dose of radiation, and is used to make a range of articles free of contamination. Sterilisation of medical and surgical products is the application of ionising

radiation in which the largest radiation sources are currently used. It reportedly has a number of advantages over other forms of treatment. These advantages include its suitability for sterilising a large number of materials as it causes no significant temperature rise and therefore permits the sterilising of heat sensitive drugs, low melting point plastic articles and biological preparations.

2.15 Gamma radiation can reach all parts of the medical and surgical objects being sterilised and they can be prepackaged to save many otherwise necessary procedures. The chemical reactivity of radiation is low compared with highly reactive gases. Also a greater freedom in the selection of suitable packaging material is a benefit that is not available with heat or gas sterilisation. The effect of radiation is instantaneous and simultaneous in the whole product and a defined dose can be used. The process is considered the most reliable sterilisation method due to the absolute certainty that the source emits radiation of known energy and power. It can also be easily adapted for continuous processing.

2.16 Preservation of a food can be achieved at a lower dose level than is required for sterilisation of other products and is used to prevent food spoilage by micro-organisms or insects in the period between harvest and eating. Ionising radiation can also be used on frozen products without affecting the freezing process. Moderate dose applications from 1 to 10 kilogray (kGy) can be used for extending shelf life of products or to eliminate sensitive food pathogens. The gray is the unit used to measure energy deposition in the material being irradiated. One gray is equal to 1 joule of energy deposited per kilogram of substance irradiated.

2.17 Disinfestation is an important factor in the use of irradiation for conserving produce and increasing market value, and helps to combat quarantine restrictions. Disinfestation is achieved by applying a lethal dose to the insect known to infest

particular produce which therefore interferes with the life cycle of the insect either by killing it at the pre-adult stage or rendering an adult sterile.

Industrial Applications

2.18 Some manufacturers use ionising radiation in a range of industrial applications based on the chemical reactions produced. These are mainly from electron beam sources. This method is a modern cost effective way of inducing chemical change and uses less energy, has higher through put, less scrap, less environmental impact, requires less floor space, is more versatile, has lower costs and on line processing is facilitated.

2.19 In industrial applications radiation effects are produced at rates comparable to manufacturing output of other industrial techniques. Therefore both the energy - to ensure proper penetration through products - and power - to ensure adequate throughput - play important roles.

2.20 Gamma radiation's main application is for industrial sterilisation of single use medical products. Health authorities advised the Committee that this procedure is the most efficient and safest way of sterilising medical products and of ensuring that patients and other users of the products are protected from injury or infection. Chemical or heat sterilisation is not a practical alternative, especially in large scale commercial production, and does not ensure the same degree of sterilisation so necessary for medical supplies.

2.21 Low energy EB accelerators have a very small energy range and applications are limited to irradiation of the surface layers. Applications include crosslinking of thin plastic film and thin wire insulation, curing of coatings on paper, wood, plastics and metal, silicon release coatings on paper and film, offset inks and laminating adhesives.

2.22 Higher energy EB accelerators are used by many major industries including plastics, automotive, rubber goods, petrochemical and wire and cable. The main applications include radiation crosslinking of plastics (wire and cable insulation, heat shrinkable materials, hot water polyethylene pipes, vulcanisation of rubber and modification of bulk polymers.

2.23 The throughput of product being irradiated varies directly with the power of the radiation source and inversely with the total dose delivered to the product. As a result, most crosslinking and polymerization applications utilize the readily obtainable higher capacity of electron beam accelerators, whereas the majority of sterilisation and preservation applications are accomplished with gamma irradiators.

2.24 Gamma irradiation facilities have an advantage over electron beam equipment for thick materials where deeper penetration is required. Electron beam equipment is preferred when the product is relatively thin.

Sterilisation of Medical Products

2.25 The largest area of experience with irradiation facilities is in the area of the sterilisation of sealed medical products.

2.26 The growth of cobalt 60 medical product sterilisation has been assisted by several developments, namely:

- growing recognition of the inherent reliability of the process;
- increasing availability of radiation stable plastics;
- improvement in economics of the process, and

. development of incremental dose irradiators.

2.27 It is acknowledged that radiation, as a sterilising agent, offers a number of advantages:

. it is a suitable means of sterilising many materials, except for certain plastics, glass and living cells. At the dose usually applied, radiation causes no significant temperature rise;

. due to its high penetrating ability gamma radiation reaches all parts of the object to be sterilised. The items can be pre-packed in hermetically sealed, durable packages, impermeable to micro-organisms. The convenience of packing and boxing prior to sterilisation eliminates the need for aseptic areas and procedures;

. the chemical reactivity of radiation is relatively low compared with the often highly reactive gases. Hence, the possibility of inducing a chemical reaction that may lead to disadvantageous changes in the products is minimal;

. since there is no problem similar to convection of heat or diffusion of gas the effect of radiation is instantaneous and simultaneous in the whole of the target;

. radiation can be easily adapted for continuous processing, and

. the process is the most reliable of all competing sterilisation methods due to the absolute certainty that the radiation source emits radiation of known energy and power.

2.28 Radiation sterilised medical products include: hypodermic syringes and needles; transfusion and infusion sets; surgical gloves; gauze and cotton wool dressings; medical devices and instruments; surgical kits; lancets; pharmaceutical containers; sutures; maternity and vasectomy kits; intra-uterine devices; some implants; biological and prophylactic preparations; talc; vaccines; antibiotics, and foods for pathogen-free diets, laboratory animals and some hospital patients.

Irradiation Facilities

2.29 At present there are approximately 130 commercial gamma irradiators operating in about 40 countries in the world, with an output in the order of three million cubic metres per year, and the number of electron beam machines is approaching 400. These figures do not include facilities in China which appears to have, or have under construction, eight "commercial size" irradiators.

2.30 The list of gamma plants ranges from 1 in countries such as Chile, Egypt, Greece, Israel, Korea and New Zealand; 3 in Brazil, France and South Africa; 7 in Japan; 11 in the USSR, to 40 in the US.

2.31 There are 3 large commercial cobalt 60 plants operating in Australia for sterilising medical supplies and some other products, but not food, other than laboratory animal feed. The Australian Nuclear Science and Technology Organisation also operates a small scale irradiation plant. Electron beam processing of materials is carried out by companies in New South Wales, Victoria and South Australia. There are 45 machines in Australia used for curing plywoods or insulated wire, treating textiles to be shrink or weathering resistant and vulcanising rubber and rubber products.

Induced Radioactivity

2.32 A number of people were concerned about induced radioactivity in food. Most of the evidence received during the inquiry indicated that there is no induced radioactivity and there is no problem. A more detailed discussion of induced radioactivity is at Chapter 5 and Appendix 2.

3. FOOD IRRADIATION

Introduction

3.1 The potential positive effects of treating foods with ionising radiation are stated to be:

- inactivation of micro-organisms which may contaminate food and cause spoilage;
- inactivation of food borne pathogenic micro-organisms;
- to delay ripening or senescence or to inhibit sprouting, and
- 'decontamination or disinfestation with regard to bacteria, yeasts, moulds and insects.

3.2 The objectives and radiation doses are shown in Table 2. While most press reports on food irradiation seem to emphasise its use to extend shelf life, evidence received during the inquiry indicates that as far as Australia is concerned it would be used primarily for disinfestation of insect pests and perhaps to reduce levels of harmful bacteria in a limited range of foods.

TABLE 2
RADIATION DOSES USED FOR TREATING FOODS

Dose Range (kGy)	Objectives	Examples and Applications
0.05 - 0.15	Extension of storage life by inhibition of sprouting	Potatoes, onions, garlic, yams
0.1 - 0.3	Destruction of parasites to prevent transmission to man through food	Meat
0.1 - 0.5	Insect disinfestation	Grains, beans, rice, flour, dried fruits, dates, coffee beans
0.075 - 1.1	Quarantine control against insect pests and plant diseases	Mangoes, beans, fruit, paw paws
0.5 - 1.5	Delay in maturation	Mushrooms, fruit
1.0 - 5.0	Extension of storage life at ambient temperatures by reducing numbers of bacteria, moulds, yeasts	Fruit, vegetables, starch
0.5 - 10	Extension of refrigerated storage life	Meat, poultry, fish
2.5 - 10	Increased digestibility. Reduction in cooking time	Soybeans, broad beans, lentils, dehydrated vegetables
3.0 - 13	Elimination of specific pathogens eg. salmonellae which cause food poisoning	Frozen meat, animal feeds, poultry, eggs, coconut, spices
35 - 60	Sterilisation of foods to allow longterm storage without refrigeration	Meat

Source: Australian Nuclear Science and Technology Organisation

Dairy Products

3.3 It is unlikely that dairy and egg products will be irradiated. Dairy products develop objectionable changes in flavour, odour and colour when irradiated at doses as small as 0.5 kilogray. Irradiation of whole eggs is not regarded as feasible as it thins the white and weakens the yolk membrane. The development of new procedures has lessened the value of using irradiation to reduce the salmonella content of processed eggs.

Meat, Fish, Poultry

3.4 The use of irradiation technology at doses which would sterilise meat, fish and poultry seems limited. Canning, freezing, dehydration and other technologies are highly developed in Australia and the Committee received no evidence from commercial sources to suggest that these traditional forms will be replaced by irradiation. Sterilising doses may be used to process light-weight foods for defence and recreational purposes and hospitals could use the process to sterilise foods for some patients.

3.5 Non-processed meat and poultry are highly perishable and may have a normal shelf life of as little as three days. Research has indicated that the shelf life can be extended by irradiation at relatively low doses but there are limits to the process. Irradiated meat and poultry at non sterilising doses still require refrigeration. They can develop off-flavours at relatively low doses. In addition irradiation only reduces spoilage by micro-organisms and spoilage by other means will still occur. Therefore irradiation of fresh meat and poultry must be combined with other measures to maintain overall quality. This could include irradiation at sub-freezing temperatures, dipping and vacuum packing. Because processing, distribution and retailing of meat and poultry is highly developed in Australia the additional costs of adding another process indicate that irradiation of these products in the short to medium term seems unlikely if the purpose of irradiation is for shelf life extension only.

3.6 There is however some commercial interest in the use of non sterilising doses to increase the shelf life of fish and to reduce the levels of harmful bacteria such as salmonella in chicken.

3.7 The literature suggests that shelf life of fish can be extended considerably but with declining quality if the product is not kept at near freezing levels. In practical terms, given the temperature fluctuations which may occur along the distribution chain, from the time of capture to immediately prior to preparation for consumption, a maximum storage life of 7 to 10 days seems reasonable. Typically some 2 to 5 days elapse prior to the fish being offered for retail sale. Research indicates that irradiation at doses between 1 and 2.5 kGy extends the shelf life at 0.6°C by at least a week and sometimes by more than 2 weeks.[1]

3.8 Some witnesses advised the Committee that irradiated fish stored at ordinary refrigerator temperatures deteriorates more rapidly than unirradiated fish. It appears however from material submitted to the Committee that shelf life extension with acceptable quality is possible. There are some adverse effects however including some flavour loss in fish and a more rapid decline in quality from spoilage mechanisms other than biological. It appears that some fish stored at 3°C and irradiated at doses up to 2 kGy is still acceptable up until 40 days later.[2]

3.9 The New Zealand study into the potential of irradiation to increase markets with fresh New Zealand fish concluded that at present irradiation of fresh fishery products to increase the shelf life does not offer clear promise of increased export returns. With the possible exception of Australia none of New Zealand's markets are close enough to be reached by ship without substantial deterioration in the quality of the irradiated product. The report further commented that there is no evidence

that a fresh product would in fact command a premium over the frozen product. No evidence was given to the Committee to indicate that the conclusions for Australia would be any different nor that the Australian consumer would prefer the irradiated product over a frozen product.

3.10 Commercial sources indicated that some frozen seafood, such as prawns, could be irradiated overseas and imported into Australia.

3.11 In terms of a reduction of harmful bacteria, such as salmonella in chicken, it is clear that irradiation could reduce the incidence of food poisoning. The Committee notes however that salmonella poisoning is generally a result of improper cooking of the chicken in the home. The Canadian House of Commons Standing Committee on Consumer and Corporate Affairs concluded that a more cost effective method to eliminate salmonella poisoning may be public education campaigns. The Commonwealth Scientific and Industrial Research Organisation (CSIRO) Division of Food Research concluded in 1982 that irradiated chicken should not be recontaminated and that the storage temperature should be sufficiently low to control regrowth of any surviving salmonella. Given that refrigeration is still essential CSIRO believed that adequate refrigeration up until the time of preparation for the table should be sufficient protection against this problem.[3]

Grains

3.12 Proper storage at low moisture levels effectively prevents spoilage. Grains however are subject to insect damage. The prime interest in grain irradiation is for insect disinfestation. A dose of 0.5 kGy is considered sufficient to control beetles and immature stages of moths. While one witness advised that irradiation can affect dough quality of flour milled from wheat[4] one author states that low doses do not affect the sensory or functional properties of grains.[5]

3.13 The Committee was advised that the USSR uses irradiation to disinfest imported wheat. It is unlikely that grains would be irradiated in Australia.

Spices

3.14 Spices can be contaminated with both bacteria and moulds and in some cases insects may be present. Irradiation accomplishes the needed reduction of microbial content of spices without causing chemical changes which can significantly affect their normal sensory characteristics and uses. Should food irradiation be approved in Australia it is possible that some spices imported into Australia will have been irradiated at point of export.

Fruit and Vegetables

3.15 None of the evidence suggests that high sterilising doses will or could be used for fresh fruit and vegetables because the product can not tolerate the higher dose.

3.16 The keeping qualities of some fresh fruit and vegetables can be enhanced by irradiation at low doses through sprout inhibition, delayed ripening and decay control. The radiation dose employed to delay ripening or other effects operates not on microbial contaminants but on the foods themselves and accomplishes the desired result by acting upon one or more biological processes of still living fruits or vegetables. In the case of delaying decay irradiation acts on the moulds or bacteria infesting the product. The difference between the dose required for treating a product for technical effect and the product's own dose tolerance level is extremely small for most fruits and vegetables.

3.17 The United States Atomic Energy Commission (AEC) funded studies on shelf life extension of fruits and vegetables during

the 1960's and 1970's. Previous studies had indicated that radiation technology could be used to extend the shelf life of a wide range of fruits and vegetables. The ability to translate these results to commercial practice however was questioned in that they did not expose the product to the injury associated with normal transport and marketing.[6]

3.18 The extensive studies duplicated product maturity, packing, handling and storage, commercial conditions and practices. The results of the investigations are summarised in Table 3.

3.19 The researchers concluded that irradiation has technical promise but only for a few commodities and that economic feasibility reduces possible application even further. Strawberries were the only domestic (US) commodity with even a remote potential for commercial irradiation if extended shelf life is the sole purpose for irradiation. In general the researchers found either that the product did not tolerate the doses required to achieve the desired effect or that there were cheaper and more effective alternative treatments.

3.20 While this research was conducted more than a decade ago the Committee received little evidence during the inquiry which contradicted these results. It is apparent that while some fruits and vegetables could be irradiated to extend their shelf life (e.g. potatoes, onions and berry fruit) the prime purpose, at least in Australia, would be for insect disinfestation.

TABLE 3

COMPARISON OF MAXIMUM TOLERABLE DOSES AND MINIMUM DOSE REQUIRED FOR DESIRED TECHNICAL EFFECTS ON SELECTED FRESH FRUITS AND VEGETABLES

Commodity	Desired technical effect	Estimated maximum tolerable dose (Krad)	Estimated minimum dose required (Krad)	Phenomena limiting commercial application
Apples	Control of scald and brown core	100–150	No effect below 150	Cheaper, more effective alternatives, tissue softening
Apricots	Inhibition of brown rot	50	200	Tissue softening
Asparagus	Inhibition of growth	15	5–10	Economics, short season, small acreage
Avocados	Inhibition of ripening	25	None applicable	Cheaper, more effective alternatives, browning and softening of tissues
Bananas	Inhibition of ripening	50	30–35	Cheaper, more effective alternatives
Boysenberries	Inhibition of grey mold	100	200	Tissue softening
Cantaloupes	Inhibition of ripening	200	No effect below 200	Cheaper, more effective alternatives
Lemons	Inhibition of penicillium rots	25	150–200	Severe injury to fruit at doses of 50 Krad or more, cheaper, more effective alternatives
Limes	Inhibition of penicillium rots	25	150–200	Pronounced off-flavours, cheaper, more effective alternatives
Mushrooms	Inhibition of stem growth and cap opening	100	200	Cheaper, more effective alternatives
Nectarines	Inhibition of brown rot	100	200	Tissue softening
Oranges	Inhibition of penicillium rots	200	200	Cheaper, more effective alternatives, no technical effect under commercial conditions
Papayas	Disinfestation of Hawaiian fruit fly	75–100	25	Economics, inadequte acreage
Peaches	Inhibition of brown rot	100	200	Tissue softening
Pears	Inhibition of ripening	100	250	Abnormal ripening, cheaper, more effective alternatives
Potatoes	Inhibition of sprouting	20	8–15	Cheaper, more effective alternatives
Raspberries	Inhibition of grey mold	100	200	Tissue softening
Strawberries	Inhibition of grey mold	200	200	Cheaper, equally effective alternatives
Table grapes	Inhibition of grey mold	25–20	1000	Tissue softening, severe off-flavours, cheaper, more effective alternatives
Tomatoes	Inhibition of alternaria rot	100–150	300 +	Abnormal ripening, tissue softening

NOTE: 10 Krad = 0.1kGy

Source: Maxie et al "Infeasibility of Irradiating Fresh Fruits and Vegetables", Hortscience, Vol. 6(3), June 1971

Disinfestation and Quarantine

3.21 Chemical fumigation is one of the means by which fruits from insect infested areas have been treated to allow entry into non infested areas. A major treatment is ethylene dibromide (EDB) which has now been banned in the United States. Other countries are currently reviewing its use. Another major fumigant, methyl bromide (MB), is currently under review. These events have resulted in the examination of alternative methods of treatment. Because tropical and sub-tropical fruits do not tolerate physical and chemical treatments well increased interest is being shown in irradiation technology. It was argued that irradiation technology will not only enable existing markets to be maintained but also open up new markets which are currently unavailable because of quarantine requirements.

3.22 According to the Committee of Direction of Fruit Marketing (COD) irradiation appears to be the only disinfestation process that can render mangoes free of both the Queensland fruit fly and mango seed weevil. The presence of fruit fly means that Queensland tomatoes are generally excluded from markets in South Australia, Tasmania and Western Australia. Additionally, replacement of the current chemical treatments required for tomatoes by irradiation for markets in Victoria and New Zealand would enable further expansion opportunities in these markets.

3.23 The New South Wales Department of Agriculture believes that irradiation disinfestation could open export markets for such products as mangoes, citrus fruits, strawberries, blueberries, cherries, asparagus and tomatoes.

3.24 The Committee was advised that there are considerable problems with the use of irradiation technology for disinfestation purposes. Doses required are considerably lower

than those used for shelf life extension. Even so, in some cases these doses cause irradiation injury. Mangoes were described as the "success story" of food irradiation[7] and are the main reason for the interest of COD in the technology. Yet the studies sponsored by the Queensland Department of Primary Industries suggest that Australian varieties may be unsuitable for the process.

3.25 The Queensland studies indicated that because a particular variety of fruit or vegetable has been successfully irradiated overseas this will not necessarily be the case with Australian varieties. The co-ordinator of the Queensland Department of Primary Industries studies stated that:

> "My results amplify the fact that irradiating at perhaps only one or two days apart can have quite substantial differences in the ultimate outcome. This is why I have serious reservations about trying to translate this technology into the industrial domain, quite apart from the fact that the plant must be centralised and the mangoes, most likely, would be 1000 miles distant."[8]

3.26 The research conducted by the Queensland Department of Primary Industries into irradiated mangoes has indicated that there are considerable problems with the Australian varieties, particularly as the aim is to export a high quality product to northern hemisphere markets. The Queensland Government is conducting extensive research into a number of horticultural products. Notwithstanding these problems a private firm in Queensland, subject to approval being given to irradiation, proposes to establish a small machine based commercial facility which will irradiate flowers and strawberries for export. The Committee also notes that South Africa and the United States have successfully marketed irradiated strawberries and mangoes.

3.27 A United States Department of Agriculture (USDA) official told the Committee that once costs, logistics and the regulatory aspects had been worked out irradiation technology is one of the brightest prospects for general use in international quarantine that has been presented to regulatory authorities. The Queensland COD believes that irradiation for infestation and quarantine purposes will not only improve international trade but will also have significant implications for trade between the Australian States.

3.28 The Committee also received evidence which indicates that more data is required before the general use of irradiation for quarantine purposes will be accepted. The problems associated with radiation injury have been discussed in previous paragraphs. The other problems relate to the pests themselves. Given the vast diversity of insect pests in the world, it is important to know how data from one species can be applied to species within a group. Fruit flies all appear to be affected in much the same way by irradiation but insufficient data exists on other groups. If a consignment has been irradiated and a species on which no data exists is intercepted later a further disinfestation treatment will be required.

3.29 As EDB has been withdrawn by the United States, and other countries are likely to follow suit, irradiation offers an alternative for disinfestation provided that technical difficulties relating to quarantine protocols and questions relating to consumer acceptance and safety can be overcome. The difficulty for point-of-entry inspectors in determining whether or not a live insect on products that have been irradiated is sterile or not, is one of the most practical difficulties hindering the more widespread use of irradiation for quarantine purposes. Irradiation will make it difficult to be absolutely sure that all of a consignment has been treated exactly as reported by an exporter or the certifying authority. If part of a

shipment is not treated, but is labelled as if it had been treated, and if a pest is present, a major difficulty will be posed for the receiving country. This could be overcome if there was a simple, foolproof test for sterility. Unfortunately the diversity of insect makes it very difficult to provide such tests for all the species likely to be encountered.

3.30 Some chemical treatments leave residues which not only allow quarantine inspectors to determine whether the product has been treated but also protects against reinfestation. This is not the case with irradiation, therefore proper handling and storage is essential.

3.31 A further problem is that there is no routine manner to determine whether or not the product has been treated in accordance with agreed procedures and doses. The Commonwealth Department of Primary Industry and Energy acknowledged that irradiated produce could present problems to quarantine officials. These problems however are not unique to irradiation. Departmental witnesses advised that while it is possible to determine that a fumigant has been used on an imported product it is not possible to determine that the process has been carried out safely and effectively. Quarantine officials rely on certificates supplied with the product. A United States quarantine official confirmed that to ensure quarantine requirements were met on-the-spot inspection at the time of irradiation would be undertaken, a procedure which is standard for many types of existing treatments.

Markets

3.32 The Committee notes that there are differences of opinion relating to the need to irradiate produce within Australia for quarantine purposes for the international and domestic markets. COD advised the Committee that markets for Queensland produce are severely limited because of the fruit fly.

If EDB was banned alternative disinfestation procedures for a number of Queensland products would need to be found. The Committee considered two major factors; first the implication for existing markets if EDB and MB were banned and secondly the implication for new markets if irradiation were approved in Australia.

3.33 It is apparant that the prohibition on the use of EDB and MB would have little, if any, impact on existing overseas markets. The main markets for Australia's horticultural products are the United States, New Zealand and Japan. No products are treated with EDB for export to the United States, although the Commonwealth Department of Primary Industry and Energy advised that citrus fruit exported to Japan may be treated with methyl bromide by Japanese authorities. The Committee understands that Australia fumigates very little grain.

3.34 The situation with existing domestic markets is similar. The Victorian Government substantially revised the inter and intra State quarantine regulations of fruit fly host produce. These changes have virtually eliminated the need for fumigation treatment of produce. In summary, the requirements are for a certificate of freedom of fruit fly, a declaration that an approved treatment has been given or, in the case of bananas and tomatoes, that they have been picked green. Produce may also enter subject to inspection. In addition, all produce is allowed free entry during May, June, July and August. At present virtually no produce is being fumigated with ethylene dibromide or any other fumigant in New South Wales or Queensland for interstate trade to Victoria. South Australia requires EDB treatment of bananas. Tasmania requires EDB treatment for produce imported from Queensland and northern New South Wales. In 1986 this amounted to only 47 tonnes of produce.

3.35 While existing domestic and international markets for Australian produce would not be significantly affected by the

prohibition of the use of chemical fumigants it was argued that extensive new markets, both within Australia and overseas, would be available if irradiation was approved for disinfestation purposes. However this argument assumes that irradiated food would be accepted by all Australian States and Territories and other countries.

3.36 COD advised that horticulture is one of Queensland's major industries and production of fruit and vegetables has expanded steadily in recent years. Quarantine regulations are considerably narrowing the range of products which can be marketed by Queensland in many important overseas markets and in other States of Australia (apart from New South Wales which has similar disease and insect pest status to Queensland). Access for Queensland grown fresh fruits and vegetables to the potentially valuable American, Japanese, Canadian and New Zealand markets, and southern/western Australian markets, is currently either severely restricted or precluded. The presence of fruit fly in the State's major tomato producing regions means that Queensland tomatoes are virtually excluded from several States.

3.37 A United States Department of Agriculture official told the Committee that while no Australian exports to the United States are fumigated, restrictions on Australian produce amounts to a quarantine barrier on a considerable number of products which would be marketable. Most States and the Northern Territory believe that irradiation has some potential to expand markets. Only Tasmania doubted that the potential benefits would be realised in practice.

3.38 A New Zealand Government Inquiry into food irradiation observed that many food exporters promote New Zealand products using the image of a clean, fresh and natural environment. The inquiry concluded that one result of the use of irradiation could be that New Zealand's clean, fresh and natural image could be sullied and trade advantages could suffer.[9] One witness advised

that Australia is increasing its markets for product in post Chernobyl Europe because of Australia's ability to export "clean" food.[10]

3.39 It is not clear how extensive the market for irradiated products could be. Some countries do not accept produce no matter how it is treated if it is grown in an area which is not pest free. These countries will not necessarily accept produce which has been irradiated. Although over 30 countries have approved food irradiation on either a conditional or unconditional basis, a survey undertaken by the USDA's Foreign Agricultural Service has revealed that, at this stage, few, if any, countries have legislated to permit the importation of irradiated foods. The USDA Foreign Agricultural Service concluded that the current potential for international trade:

> "is very limited at best and, for the most part, non-existent".[11]

3.40 According to the Department of Primary Industry and Energy this situation is likely to remain in the foreseeable future given the lack of international inspection protocols, the absence of reliable dosimetry methods to validate actual radiation doses applied and the controversy surrounding the comparative safety and wholesomeness of irradiated foods.

Alternatives to Irradiation

3.41 A number of organisations suggested that there are viable alternatives to irradiation for shelf life extension, elimination of harmful bacteria and disinfestation. The Committee observed in paragraph 3.11 that proper processing, handling and education may be more effective alternatives to food irradiation in the prevention of food poisoning. The evidence also suggests that shelf life extension (at least in Australia) is only a secondary interest of those who are supporting the process,

therefore alternatives which are aimed at increasing shelf life are not directly relevant to these investigations. Treatment of agricultural produce to control pests seems to be the main argument for the introduction of radiation technology.

3.42 The alternative treatments to irradiation are fumigation, physical methods, such as temperature and atmosphere, and biological controls. A more detailed discussion of the alternative treatments is shown at Appendix 3. In summary the Committee was advised that many of the treatments proposed are already widely used in Australia. Methods are constantly under review and new techniques are being developed. However many of the treatments are limited in their application and are only suitable for some products and in some circumstances are uneconomic. Further advice was that some of the procedures outlined are unacceptable to overseas quarantine authorities.

3.43 Witnesses advised that while irradiation is not suited to all fresh horticultural commodities it can be seen as a more effective disinfestation treatment against pests in a large range of produce than any other alternative so far devised.

Economics

3.44 Information available on the costs of food irradiation is limited. Few commercial food irradiation facilities are in operation around the world and consequently little practical information exists to evaluate the cost effectiveness of using ionising energy to treat specific products in comparison with competing chemical treatments and other alternative processes.

3.45 The estimates of both capital costs and running costs of a food irradiation facility vary quite significantly. The real costs cannot be specified in any general way for the whole technology, but need to be calculated for each individual proposal, using relevant data. The costs of any specific proposal

will consequently be a function of the type of facility, but this calculation excludes the extra transport costs involved in a large facility. Multipurpose facilities on the other hand are inevitably more expensive than custom built plants for specific tasks, but may be less expensive if there is not enough produce all year to supply a facility for food only.

3.46 Food irradiation technology requires a substantial capital outlay. Overseas studies indicate that the capital cost (excluding land) of a small irradiator is approximately $1 million while a large, automatic irradiator may cost as much as $4 million. Operating costs can also be significant - one study estimated that they might range from $600 000 to $1.2 million for the first year of operation, depending upon the size of the irradiator. High capital and operating costs are likely to preclude many companies from setting up irradiation facilities.

3.47 Chinese authorities consider that irradiation is an effective means of food preservation. Operating and capital costs do marginally increase food costs but this is acceptable to overcome food shortages and other problems such as the lack of refrigeration.

3.48 It is not clear whether demand is sufficient in any region of Australia for large scale irradiation to be undertaken. Data available shows that the cost of irradiating food is critically dependent on both the radiation dose used for the particular application and the volume of produce handled by the plant. Depending on the particular case the direct costs quoted in the literature range from 3 cents to almost 30 cents per kilogram of food treated. Costs in the lower part of this range appear to be dependent on economies of scale which might not be achieved in Australia, given proposed useage. Notwithstanding these comments one company in Queensland has conducted feasibility studies on using a machine facility. Their calculations indicated that for high quality, high priced products, costs are acceptable and could be readily absorbed by the market.

3.49 The International Finance Corporation which is an affiliate of the World Bank, advised that it had intensively studied the subject of food irradiation in developing countries and found that none of the projects met its stringent standards. This evaluation involved a close scrutiny of all economic, financial, environmental and safety aspects. The Corporation believed that to date food irradiation projects had not measured up to the Corporation's investment standards and criteria.

3.50 The manager of two commercial medical products irradiation facilities operating within Australia confirmed that the economics of food irradiation are marginal at the best.

World Hunger

3.51 While the previous discussion indicates that food irradiation will have limited application in Australia, proponents have stated that it will assist in overcoming world hunger. The proponents recognise that on the basis of figures for world-wide production of food and total world population there is sufficient food. They point out however that a satisfactory distribution between surplus and needy areas is a prerequisite for coping with malnutrition and this could be alleviated if food losses were reduced by radiation treatment or some other appropriate storage treatment.

3.52 Accurate estimates or reports of the extent of post harvest storage losses in developing countries are difficult to obtain. Some estimates indicate that approximately one quarter to one third of all production is lost, after harvesting, due to spoilage.

3.53 The Committee was advised that it is even more difficult to estimate the extent to which post harvest spoilage results in subsequent illness of the population. However it is known that

parasitical diseases are very common in developing countries. It was concluded that the successful application of radiation technology to achieve an increase in useable supplies of food, through reduction in post harvest spoilage and possible consequent health benefits, would depend on the economic and political conditions prevailing in a particular country. Such important considerations do not, it was concluded by some authorities, detract from the potential of radiation technology to make a significant contribution to solving the problems of the world's food supply by assisting in preserving in a wholesome state a larger proportion of food produced in the world.

3.54 There were many who totally reject this view. The problem of world hunger, it was argued, is not caused by inadequate food production or technology. Each year billions of dollars worth of food is dumped by the European Economic Community (EEC) alone. The resolution of the problem of world hunger lies not in a technological fix but in a more equitable distribution of the world's resources and a shift from spending on armaments to spending for human needs.

3.55 Third World hunger arises partly because of inadequate or outmoded transport, lack of refrigerated storage and generally high temperatures and humidity. In certain developing countries, which rely mostly on self sufficiency and lack an adequate national food system infrastructure, a food irradiation facility could become an expensive anomaly. In such countries food irradiation processing plants can be considered only as part of a national agricultural development program.

3.56 Appropriate refrigeration, storage and warehousing must be developed to prevent recontamination. Adequate transportation networks and collection and distribution centres must be created to ensure that sufficient volumes of food can be hauled to an irradiation facility to make it economically viable. In fact the reasons for food shortages are in part the result of the lack of

the facilities that would be required to service irradiation facilities. The establishment of sufficient distribution networks, refrigeration and other storage facilities would significantly decrease food shortages without the need for food irradiation.

3.57 It is also important to note that food irradiation without proper post treatment handling and storage would not prevent reinfestation.

3.58 The Committee is of the view that food irradiation would have only a marginal impact on Third World hunger and health.

Conclusions

3.59 Industry sources clearly recognise that a number of products are totally unsuitable for irradiation. They have submitted that as with traditional forms of food processing only those suitable would be irradiated. It is clear from the evidence however that many people are concerned that irradiation technology could eventually be applied to a wide range of products.

3.60 While food irradiation is apparently commercially successful overseas the application to Australia seems extremely limited. For most applications there are effective and more economic alternatives.

3.61 The Committee also notes evidence which suggests that there are considerable problems relating to handling, transport and processing. Irradiation plants overseas have overcome these problems for a limited range of products, such as strawberries and perhaps mangoes. Technical solutions may also be found in Australia. It is the Committee's view that for technical reasons only an extremely limited number of products could be irradiated and those primarily for disinfestation purposes for export.

3.62 Industry sources claimed a limited amount of irradiated product could be sold in Australia, primarily tropical fruits and tomatoes. It was also claimed that, in the longer term, irradiated packed boned chicken and perhaps fish could be available to the Australian consumer.

3.63 Apart from some primary producer and marketing organisations there is little interest in the technology. The Grocery Manufacturers of Australia told the Committee that they have no policy or interest in any particular use for irradiation. It could however be used to disinfest spices should approval be given by Australian authorities. The irradiation treatment would be undertaken at the port of export.

Endnotes

1 Transcript pp. 889-909.
2 Wills, P.A. et al, "Technology Transfer for Ionising Energy Treatment of Foods in Australia", RPFI, Phase II, 1987.
3 Transcript p. 910.
4 Transcript p. 3867.
5 Urbain, W., Food Irradiation, Academic Press, 1986.
6 Maxie et al, "Infeasibility of Irradiating Fresh Fruits and Vegetables", Hortscience, Vol. 6(3), June 1971.
7 Transcript p. 2230.
8 Transcript p. 2235.
9 New Zealand Ministry for the Environment, "Food Irradiation and Industrial Radiation Processing in New Zealand", Feb. 1988.
10 Transcript p. 3733.
11 Food Chemistry News, 1 June 1987.

4. ASSESSMENT OF FOOD IRRADIATION

Introduction

4.1 The Codex Alimentarius Commission (Codex), which is the governing body of the Joint Food and Agriculture Organization (FAO) and the World Health Organization (WHO) Food Standards Program, has developed an international code relating to irradiated food standards and codes of practice and labelling. These codes are based on the assessments and recommendations of the International Food Irradiation Project (IFIP) established in 1970 and Joint Expert Committees of the FAO, WHO and the International Atomic Energy Agency (IAEA).

4.2 In addition food irradiation has been assessed by Parliamentary Committees, scientific panels and government agencies in a number of countries, including Australia.

4.3 In 1961 the FAO, WHO and IAEA sponsored a meeting on the wholesomeness of irradiated foods. The purpose of the meeting was to allow a free exchange of ideas amongst scientists concerned with research on the wholesomeness of irradiated food and representatives of public health and food administrations. The objective was to reach conclusions on the nature of the experimental evidence required to provide the technical basis for a common approach to the formulation of national legislation on the production and use of irradiated foods. The meeting concluded that more specific chemical and biological research is required on the effects. It recommended that an expert committee be established to assess data relating to food irradiation.

4.4 In response to this recommendation a Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI) was established. The Committee met in 1964, 1969, 1976 and 1980.

4.5 The following discussion relates to the more recent examinations of food irradiation.

JECFI 1964

4.6 The 1964 meeting concluded that before any legislation was enacted to permit irradiation of food there should be clear evidence that any disadvantages which might possibly arise are substantially outweighed by the special advantages. In particular no known hazard to health should be introduced either during application of the treatment or in the utilisation of the product. JECFI recommended that the use of ionising radiation for the treatment of food should be under legislative and public health control and should be permitted only after evidence, regarding the safety for consumption and nutritional value of the product, had been accepted by the appropriate government authority. JECFI recommended feed trials along the lines which would be applicable to any chemical or additive to a food and also biochemical studies to determine the changes in the foods.

JECFI 1969

4.7 The 1969 meeting examined the wholesomeness of irradiated food with special reference to wheat, potatoes and onions. JECFI concluded that although no positive evidence of harmfulness had been found the available data contained ambiguities and were sometimes lacking in precise detail. While JECFI considered that too little information was available at that time to establish general principles for extrapolation of data on the wholesomeness of some irradiated foods, it concluded that data on the wholesomeness of one irradiated food had relevance to other irradiated foods. It recommended further studies, including studies of mutagenicity.

JECFI 1976

4.8 The 1976 meeting reviewed and evaluated the existing data on irradiated foods. This had been gathered mainly by the International Food Irradiation Project which had been established to answer the wholesomeness and safety questions about the process. The meeting was presented with evidence on the great similarity in radiolytic products in related foods treated with radiation doses of the order of 10 kGy and on the uniformity of reaction of protein, lipid and carbohydrate constituents of foods to irradiation. It considered therefore that it was possible to generalise to a considerable extent about the radiation chemistry of foods. Most of the radiolytic products identified in irradiated foods, JECFI concluded, could also be found in non-irradiated foods and many of them are generated in foods by other processing procedures.

4.9 For those radiolytic products that had been identified the concentrations of the most abundant, even with radiation doses of up to 60 kGy, were only in the mg/kg range. With dose ranges below 10 kGy, that is, in the range which achieved the technical requirement for foods considered by the meeting, the concentrations of radiolytic products would be much lower. The meeting concluded that the available data on the chemical structures of radiolytic products in food and the very low concentrations in which they occur suggested the general conclusion that the health hazard they might represent was negligible.

4.10 From such considerations JECFI envisaged that for doses of up to 5 kGy, chemical data along with evidence from animal feeding studies, may eventually indicate that food items in general would be safe for consumption by humans. If certain radiation, chemical and toxicological studies were continued it may even prove possible to use the purely chemical approach to the

wholesomeness evaluation of irradiated foods. It commented however that the acceptance of these principles would not militate against the questions which might be asked about any new process. Thus irradiation must be proved to be an acceptable means of processing food and one which does not impair its wholesomeness and it may be premature to base an evaluation for the new irradiated food solely on data obtained with other foods, even though they may be of closely related types.

4.11 JECFI recognised the problems associated with treating irradiated foods as additives and acknowledged food irradiation as a process. Unconditional acceptance was given for irradiated wheat, potatoes, chicken, papaya and strawberries and provisional acceptance of irradiated cod and redfish. Additional areas were identified where further research was required, particularly radiolytic products, combination processes and fats.

JECFI 1980

4.12 Since the previous meeting a large number of data on irradiated foods and food components had been generated. The 1980 meeting was convened to evaluate the wholesomeness of the irradiated foods for which data was available. It concluded that irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard and that irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems. No further toxicological testing of food so treated was required. It believed that there were two areas where further research was required, namely the technological and economic feasibility of food irradiation on an industrial scale, including a study of a wider variety of foods with respect to their suitability for processing by irradiation, and investigations into the use of high dose radiation for the treatment of certain foods.

4.13 One of the most significant conclusions of the 1980 meeting was, that contrary to the opinion expressed by the previous meetings, it was practical to stipulate an average dose rather than to require that no part of the food shall receive less than a minimum or more than a maximum dose.

Codex Alimentarius Commission

4.14 The Codex Alimentarius Commission is the governing body of the Joint FAO/WHO Food Standards Program. Codex was established in 1962 with the objective of co-ordinating and rationalising international activities in food standardisation. In 1983 Codex adopted the recommendations of the 1980 JECFI. The standard approved the unrestricted use of irradiation on any food up to a maximum absorbed dose of 10 kGy. The actual dose applied depends on the intended processing or public health purpose and the tolerance of the food to irradiation. Lower doses are appropriate for many purposes. Codex has noted however that JECFI left the door open to future approvals of higher doses by stating in the introduction to the standard that the 10 kGy value "should not be regarded as a toxicological upper limit above which irradiated foods become unsafe; it is simply the level at or below which safety has been established".

4.15 The 1980 JECFI concluded that while foods should normally be irradiated only once, in certain circumstances repeated irradiation might be justified. Under the Codex standard re-irradiation is allowed for the following foods:

- low moisture foods irradiated for insect control;
- food prepared from materials irradiated at doses around 1 kGy;
- food containing less than 5 per cent of irradiated ingredients, and
- foods where the full dose is applied in instalments for a specific technological purpose.

4.16 The cumulative overall average dose was not however to exceed 10 kGy.

4.17 The Codex recommendations on irradiated foods have now been distributed to its 129 member governments for acceptance, and were the basis for the National Health and Medical Research Council's model food irradiation regulations.

European Parliament

4.18 Three Committees of the European Parliament have examined the question of food irradiation, namely, the Committee on Energy, Research and Technology, the Scientific Committee on Food and the Committee on the Environment, Public Health and Consumer Protection (EPHCP).

4.19 The Energy, Research and Technology Committee noted that research was being undertaken and should continue into the technological and economic feasibility of irradiation on a large scale and irradiation of a wider range of food, wholesomeness assessment of certain foods of radiated doses higher than 10 kGy, publication of conflicting results as to the effect of radiation on the biological value of proteins and vitamins (such as folic acid) and the effects of the combination of irradiation with other processes on the nutritional value and wholesomeness of food. The Committee believed that further research was required to reduce any nutritional or flavour damage to the food, to ascertain more exactly the effects of combining irradiation with other preservation systems and to study the impact on any nutritional losses on people who live on low incomes and restricted diets in Europe and elsewhere. Notwithstanding these comments the Committee concluded that JECFI and FAO had already established that safety aspects were satisfactorily covered provided certain radiation limits were observed.

4.20 The Scientific Committee on Food, after examining data collected by the International Food Irradiation Project and reports of JECFI, concluded that on the basis of all the information reviewed, in the context of an overall assessment of the wholesomeness of irradiated foods only those specific irradiation doses and food classes should be endorsed that were indicated as appropriate, not only from a strict toxicological point of view but also from a chemical, microbiological, nutritional and technological stand point. The following table lists the food classes and radiation doses considered to be acceptable from a public health stand point.

TABLE 4

FOOD CLASSES AND RADIATION DOSES

Food Class	Overall Average Radiation Dose (kGy)
Fruits	up to 2
Vegetables	up to 1
Cereals	up to 1
Starchy tubers	up to 0.2
Spices and condiments	up to 10
Fish and shellfish	up to 3
Fresh meats	up to 2
Poultry	up to 7

Source: The European Parliament Scientific Committee on Food

4.21 The Scientific Committee also had no objection to considering an extension of the list to other applications provided that appropriate information was given for evaluation.

4.22 The Committee on the Environment, Public Health and Consumer Protection reached conclusions which differed significantly from those of the other two Committees. The EPHCP Committee examined documents which were related primarily to studies and views which indicated adverse effects of food irradiation on the product and on test animals. The EPHCP Committee concluded that despite decades of research it was not possible to prove that food irradiation causes no harm to health. The EPHCP Committee stated that practically all scientific studies admit a considerable degree of uncertainty as regards effects on human health. The EPHCP Committee was concerned that there was no routine way to assess whether or not food had been irradiated and that the process could be used to deceive consumers with regard to freshness or ripeness. It concluded that the use of ionising radiation to conserve food is potentially more dangerous than conventional methods and that workers in radiation plants are exposed to greater risks. As a method of conservation, radiation was no better or cheaper than other methods and the technological improvements to certain foods were of interest to manufacturers but not to consumers.

4.23 The EPHCP Committee rejected the general authorisation of irradiation as a method of conserving food and called on the member states of the European Economic Community to ban the irradiation of foodstuffs, prohibit the import of irradiated food and animal feed from non-member states and prohibit the export of irradiation equipment to Third World countries.

4.24 On 10 March 1987 the EEC adopted an opinion on irradiation. The resolution seems to be a compromise between the various views of the Committees. The resolution stated that before irradiated foods are freely traded in the Community the European Commission must clarify whether it is possible to determine scientifically whether a food or food ingredient has been irradiated and if so, at what dose. On precautionary grounds the

Parliament rejected the general authorisation of irradiation as a method of conserving food, believing that the shortcomings in the conservation of food could be removed more satisfactorily by other methods. The Parliament conceded however that irradiation can complement traditional methods of conserving and processing. The resolution called for the Commission, if it proposed free trade in irradiated foods, to develop a system of compulsory labelling of such foods. It also recommended that if food irradiation was approved the Commission should cite the scientific findings on which it based its decision.

4.25 The European Commission is at present considering regulations relating to trade in irradiated food.

United Kingdom

4.26 Following the publication of the 1980 JECFI report the British Government in 1982 established an Advisory Committee on Irradiated and Novel Foods (Burgen Committee). The Advisory Committee reported in 1986.

4.27 The Burgen Committee concluded that it was satisfied from their review of data that ionising radiation up to an overall average dose of 10 kGy, correctly applied, provides an efficacious food preservation treatment which would not lead to a significant change in the natural radioactivity of the food or prejudice the safety and wholesomeness of the food. The Burgen report noted that irradiation can be used to extend shelf life and more importantly, in relation to public health, can be used to kill or reduce the numbers of pathogenic and spoilage organisms in a variety of other products. It also provides an effective alternative to chemical treatments for the control of insect infestation of grain and other stored products. The Burgen Committee was satisfied that there was no justification on public health grounds for the present United Kingdom regulations prohibiting the use of ionising radiation.

4.28 The Burgen report commented that if it was agreed that food irradiation should be permitted in the United Kingdom procedures should be established to monitor the consumption pattern of irradiated foods and their nutrient content to detect any unforeseen nutritional consequences. There would equally be a need to review new toxicological data on irradiated foods and to consider any toxicological implications of new applications of food irradiation, which might be revealed by monitoring the extent and pattern of its use.

4.29 The Burgen Committee was satisifed that there were no scientific or public health reasons which would require an indication at the point of retail sale that a food had been irradiated. It noted however that the Food Advisory Committee, which was requested by the Burgen Committee to consider the question of labelling, recommended that, for the purpose of informing the consumer, all irradiated foods as compound foods, containing irradiated ingredients, should bear an indication of the treatment in specified terms and that statutory provisions should be introduced to require both this and the maintenance of documentation throughout the processing chain for the identification of irradiated foods and ingredients.

4.30 A report of the Board of Science and Education of the British Medical Association believed that the Burgen report might not have sufficiently taken account of possible long term medical effects on the population. It believed that more scientific data was required and concluded that a full scale study should be undertaken in collaboration with the Medical Associations of those countries where the process was already in use.

4.31 The British Government received over 6000 letters from members of the public and some 150 from organisations commenting on the recommendations of the Burgen Committee. In a response to these letters the Burgen Committee advised that it didn't consider

that any of the comments received caused it to change the advice given in its report. It emphasised however that irradiation must not be used to attempt to make unfit food acceptable, it would be necessary to monitor the extent and pattern of use, record keeping and documentation must be adequate and food should not be consumed less than 24 hours after irradiation.

United States of America

4.32 Following extensive investigations by the United States Army, the Food and Drug Administration (FDA) in 1963 and 1964 approved the use of ionising radiation for bacon, white potatoes, wheat and wheat products. In 1966 the Army submitted a petition to the FDA for the approval to use ionising energy for processing ham. No experimental wholesomeness data had been obtained. Since the previous approvals the FDA had altered its standards for toxicity testing. The Army withdrew its petition for ham and the FDA rescinded its approval for the use of ionising energy for bacon because the evidence submitted previously did not cover all the new criteria for toxicity testing.

4.33 In March 1982 the FDA published an advance notice of proposed regulations following the publication of the report from the United States Centre for Food Safety and Applied Nutrition and requested comments on the overall approach. In February 1984 the FDA published a proposed regulation which would establish general provisions for food irradiation, permit the use of food irradiation at doses not exceeding 1 kGy for inhibiting the growth and maturation of fruits and vegetables and for insect disinfestation of food, allow irradiation to be used for microbial disinfection of certain dried spices and dried vegetable seasonings at a dose not exceeding 30 kGy and eliminate the current irradiated food labelling requirements for retail labelling.

4.34 In April 1986 the final version of the regulation was published approving the use of doses of ionising radiation up to a maximum dose of 1 kGy to disinfest fruits and vegetables and to delay ripening and the use of 30 kGy to decontaminate spices and dry condiments. The regulation also required that foods that are irradiated be labelled appropriately, both at the wholesale and retail level.

4.35 The FDA's final regulation was reached after detailed consideration of the formation of radiolytic products, safety questions, destruction of nutrients and an examination of toxicological studies. The FDA concluded that the safety of food irradiated below 1 kGy has been established because irradiation would not make food radioactive, the chemical differences between irradiated foods processed at these doses and non-irradiated foods were too small to affect safety of the foods, food irradiated at doses of up to 1 kGy would have the same nutritional value as similar foods that had not been irradiated and the balance between microbial spoilage organisms and pathogenic organisms would not be adversely affected by radiation doses below 1 kGy.

4.36 The Council for Agricultural Science and Technology as a result of a Congressional request established a task force to prepare a report on the use of ionising energy in food processing and pest control. The task force conducted an extensive review of studies relating to food irradiation and reported in 1986.

4.37 CAST advised that the energy levels of the gamma rays, accelerated electrons and x-rays legally permitted for processing food would not induce measurable radioactivity. The compounds formed in minute amounts when ionising energy interacts with some of the food molecules had also been studied at length. The types and amounts of compounds formed have not been found to impart toxic qualities to food. Similar compounds occur in unprocessed food and in food processed by well established conventional methods.

4.38 Numerous direct feeding studies had been conducted during the past 35 years to assess the wholesomeness of food processed with ionising energy. Some had been large-scale experiments. Subjects tested included humans and various animal species. Lifetime studies had been carried out with animals (including four generations of rodents). Assessments were made of possible relationships between consumption of foods processed with ionising energy and the development of cancers, birth defects and genetic changes. CAST concluded that the results have provided no confirmed evidence that processing food with ionising energy creates these or other toxicological hazards.

4.39 CAST concluded that tests to determine the utilization of nutrients in food treated with ionising energy had disclosed no unfavourable effects in comparison with food processed by well established conventional means. CAST found no evidence to indicate that antivitamin compounds are formed by treating food with ionising energy. No evidence had been found that treating food under the proposed technology with amounts of ionising energy that did not eliminate all organisms would lead to development of radiation-resistant micro-organisms, pathogens with increased virulence, unusual spoilage characteristics, or changes in physiological characteristics of the organisms that would make them difficult to identify.

4.40 CAST concluded that from all the available scientific evidence foods exposed to ionising energy under the conditions proposed for commercial application are wholesome, that is, safe to eat. Their nutritional adequacy compares favourably with that of the fresh foods or with that of foods processed by well established conventional methods.

Canada

4.41 During the course of the inquiry two assessments by Canadian bodies were drawn to the attention of the Committee, namely a report by the Science Council of Canada on Food Irradiation, Prospects for Canadian Technology Development, and a report of the Canadian House of Commons Standing Committee on Consumer and Corporate Affairs on the question of food irradiation and the labelling of irradiated foods.

4.42 The Science Council concluded that food irradiation was a creditable option for dealing with problems of food preservation, hygiene and quarantine protection. Amongst its recommendations was a call for the health authorities to complete the process of regulatory approval of the Codex Standards, to speed up individual clearance procedures, introduce labelling requirements and that Canadian industry co-ordinate its efforts so that the manufacturing sector could remain at the forefront of technological development and commercialisation and the user industries take maximum and timely advantage of the availability of this technology.

4.43 The Standing Committee on Consumer and Corporate Affairs, as part of its investigations, conducted public hearings and commissioned toxicologists to examine some of the available data. On the basis of the toxicologists report the Standing Committee recommended that ionising energy continue to be regulated as a food additive and be restricted until an in-depth scientific assessment of health implications and further toxicological studies have indicated that no significant adverse health effects would be expected to be found. It further recommended that irradiation of wheat no longer be permitted.

4.44 The Standing Committee recommended a series of further feeding studies, examination of the incidence of polyploidy and

free radicals, the effect of irradiation on pesticide residues, and that the maximum overall observed average dose should be restricted to 1 kGy except for specifically approved situations.

4.45 While acknowledging that irradiation could reduce the incidence of salmonella poisoning, the Standing Committee recommended that more cost effective measures be pursued to contend with the salmonella problem in Canada. These methods should include the establishment of a comprehensive public education program to promote proper and safe handling techniques for poultry.

4.46 The Standing Committee further recommended that investigations be conducted on the effect of irradiation on the nutritional degradation of the foods for which irradiation is presently permitted and that further studies be conducted with emphasis placed on tests to examine the long term chronic effects of ingesting irradiated foods. The Standing Committee believed that all irradiated foods should be fully labelled, regardless of whether food irradiation continues to be classified as a food additive or a process.

4.47 While accepting the Standing Committee's recommendations relating to labelling the Canadian Government rejected all recommendations which would require further examination of the safety of the process. The Canadian Government concluded that research done in Canada and elsewhere has established the proper application of food irradiation as effective and did not pose a hazard to health. The Government advised that it saw no reason to alter current approved uses of food irradiation or to postpone the case by case consideration of any future applications.

New Zealand

4.48 The New Zealand Government has established an Irradiation Issues Working Party to provide policy advice on

irradiation technology and the appropriateness of food irradiation for New Zealand. In February 1988 the Working Party released a detailed discussion paper containing its findings and recommendations. The Working Party concluded that no significant need for food irradiation technology had been identified for New Zealand. This conclusion was based on the following points:

- very few New Zealand products are likely to benefit from irradiation at the present time;

- alternative food hygiene and quarantine methods are available and accepted under present circumstances;

- none of New Zealand's major export markets has accepted or required irradiated products;

- there is no significant need for the irradiation of local foods for local consumption;

- the acceptance of food irradiation processsing in New Zealand would have a detrimental effect on New Zealand's image and hence on all our export trade, regardless of whether or not a particular food product is irradiated, and

- there is at present a climate of consumer uncertainty about the safety of irradiated foods. While there has been no detailed survey of consumer opinion there appears to be general opposition to irradiation processing and sale of irradiated foods in New Zealand.

4.49 Since no significant need for irradiation could be identified at present the Working Party recommended that the New Zealand Government take all necessary steps to ensure that the irradiation of food for human consumption be legally prohibited.

4.50 The Working Party found that the risks posed by irradiation facilities to plant workers and the general public were extremely low. A similar conclusion was reached concerning the transport of the radioactive source. The health risks associated with the operation of irradiation plants were less than from many established industries, such as some agrochemical and energy-related industries, and were at a level which is usually disregarded in a developed, industrialised country such as New Zealand.

4.51 The Working Party noted that the majority of overseas review committees which had evaluated the safety data on irradiated foods concluded that provided there were adequate restrictions and controls, irradiated food was both safe and wholesome and was comparable with other processing methods in these respects. However, some of these committees which addressed wider issues (e.g. consumer concerns), as well as some scientists and members of the public, remained unconvinced that the safety of irradiated food had been proven and considered that further studies were required.

4.52 The Working Party could not reach unanimous agreement on the safety of irradiated food. The majority felt that there were no unacceptable risks from the consumption of foods which had been irradiated up to 1 kGy, provided there were suitable controls on the process. Some members felt there were no unacceptable risks with irradiation up to higher doses (e.g. 10 kGy, or for foods such as herbs and spices, 30 kGy). A minority of the Working Party felt that the safety of irradiated food had not been established.

Australia

4.53 The National Health and Medical Research Council (NH&MRC) established the Food Irradiation Subcommittee in 1962. This subcommittee reported to the Food Additives Committee and between 1962 and 1963 it considered the irradiation of wheat, potatoes and

bacon. In 1963 Council advised the States and Territories that it was recommended that food treated with radiation should not be approved in Australia until more information on the process could be obtained and evaluated.

4.54 Interest in food irradiation was revived in 1978 when the NH&MRC was made aware of large quantities of microbiologically contaminated prawns which had been imported. The prawns could not meet the NH&MRC model microbiological standard of the day and after consultation between industry, New South Wales and Victorian Health Authorities and the Commonwealth Department of Health, the consignment was irradiated and distributed for sale. This event was intended as a "one-off" measure and was accompanied by media coverage. The matter was referred to the NH&MRC which in June 1979 recommended that unless specifically approved no food shall be treated with ionising radiation and irradiated food shall not be offered for sale. In the same year the NH&MRC recommended that Australia participate in IFIP.

4.55 In 1981 an application for the irradiation of spices, poultry and fruit and vegetables was submitted to the NH&MRC. The Food 'Science and Technology Subcommittee (FST) of the NH&MRC took into consideration the Codex General Standard and the technological justification made in the submission and recommended "Gamma irradiation of spices, fruit, vegetables and cereals should be approved provided the dose does not exceed 10 kGy".

4.56 FST considered that the case for the irradiation of poultry had not been adequately justified and sought further information from the applicant and international authorities.

4.57 The Food Standards Committee (FSC) endorsed the FST recommendation in 1982 but did not progress it to the Public Health Advisory Committee (PHAC) because the issue of labelling had not been addressed. FSC noted that the Codex Committee on Food Labelling was currently discussing the labelling of irradiated

foods and decided to await the recommendations of that committee. However, the NH&MRC did recommend in 1982 that Australia participate in the International Consultative Group on Food Irradiation which would replace IFIP in 1984. At this time Australia was already participating in the Asian Regional Co-operative Project on Food Irradiation.

4.58 By 1983 the FSC and FST agreed that the existing prohibition for the irradiation of foods should be rescinded and the Codex General Standard for Irradiated Foods be adopted by Council. The FSC directed that a model food standards regulation based on the Codex General Standard should be prepared for its consideration. This draft was prepared and in March 1985 the FSC examined it, amended it as considered necessary and directed that it be circulated to the State and Territory Departments of Health, the Australian Federation of Consumer Organisations, the Dietitians Association of Australia and others for comment.

4.59 In June 1985 the FSC considered all the comments received on its March 1985 draft, amended it as considered necessary and again circulated it to the same organisations as above and also to the Australian Council of Trade Unions.

4.60 In March 1986 the FSC considered the comments on the June 1985 draft, finalised it and recommended it to the NH&MRC for adoption. Later in March 1986 the PHAC acting on the delegation given by Council at its Eighty-seventh Session -

(a) adopted the Model Food Standards Regulation for the Irradiation of Food recommended by the FSC in March 1986;

(b) adopted the "Format for the Application for Approval to Irradiate Food", and

(c) recommended that a Working Party be set up to devise a national consumer information program with regard to food irradiation.

4.61 In May 1986 the NH&MRC established a Working Party to develop a food irradiation information program. However the Working Party was suspended when the Minister for Health contracted with the Australian Consumers' Association to undertake a consumer inquiry into food irradiation.

4.62 ACA released its report in April 1987. Its conclusions and findings were based on an examination of research papers, submissions received and extensive discussions with scientists and community organisations in Australia and overseas.

4.63 ACA found that while most studies indicated that there was no risk to health in eating irradiated food some did indicate toxicity. ACA concluded that:

- applications for approval to irradiate a specific item of food should be accompanied by a critical evaluation of all the research pertaining to that food item;

- approval to irradiate individual food items should be accompanied by limitations to dose so as to minimise the risks to consumer health, and

- the process itself should be carefully controlled in terms of licensing and operating of facilities.

4.64 To this end the introduction of a Federal food irradiation Act was recommended to control all facets of the food irradiation industry and that the responsibility to co-ordinate all matters under the Act be vested in a national body. Ongoing representation from relevant scientific bodies, government departments and from the consumer movement was also required in formulating specific regulations.

4.65 It was recommended that extensive labelling requirements be introduced and that the use of caesium 137 be banned.

4.66 ACA concluded that as a food process irradiation has limitations. Many foods are physically altered by the process, some deteriorate during transportation after irradiation and some develop unpleasant tastes and smells. ACA observed that preliminary calculations for Australian conditions indicate that the quantities of fruit and vegetables required for economic viability are unlikely to be realised and that the transport costs involved in taking food vast distances to a centralised facility may offset the profitability of the process.

4.67 ACA believed however that research was providing solutions to overcome some of the difficulties.

4.68 ACA observed the difference in the positions of the FDA and JECFI. As a result of its review of the research the FDA reached the conclusion that food irradiation, on the whole, was safe up to a maximum dose of 1 kGy (30 kGy for spices). JECFI concluded that irradiation was safe to an average dose of 10 kGy. Although both bodies examined over 400 studies ACA advised that less than 10 per cent of the source material was common to both reviews.

General Comments on Assessments

4.69 Later chapters of the report will deal with the specific questions of safety, nutrition and regulation of food irradiation. A number of general criticisms were received and these are discussed in the following paragraphs. These concerns include the role of the nuclear industry in the assessment process, that some assessments were little more than promotional exercises rather than scientific assessments and the lack of proper referencing to enable independent assessment of the findings.

The Nuclear Link

4.70 Concern was expressed about the involvement of certain organisations in the alleged promotion of food irradiation. These organisations included the US Army, US Department of Energy, IAEA, FAO, WHO, JECFI and agribusiness. Of particular concern was the alleged nature of the involvement of the nuclear industry.

4.71 Witnesses advised that the initial push for food irradiation came in the 1950's during the height of the "atoms for peace" program in the US. The argument was advanced that at that time governments, particularly in the US and Britain, were facing increasing public opposition to their nuclear weapons programs and needed projects to justify continued expenditure on nuclear industries. Nuclear power was the main development chosen at the time, with food irradiation another. From the start most research into food irradiation in the US has been financed by the United States Army and the Atomic Energy Commission.

4.72 One witness advised that over the last 10 years there has been a steady growing opposition to the nuclear power industry. The nuclear industry needs another justification to divert public attention from their true mission of supplying the fuel for nuclear weapons. Food irradiation provides the sort of justification the industry needs. The witness argued that to reprocess fuel from nuclear reactors to attain cobalt and caesium only would be very expensive. However if the spent fuel is being reprocessed to obtain plutonium then the sale of cobalt and caesium will reduce the cost of the plutonium extraction.[1]

4.73 The storage and disposal of nuclear waste remains an unresolved problem. It was argued that a food irradiation industry based on the use of caesium has two main effects. First, it allows the stockpiles of waste to be reduced and distributed around the world and secondly, enables the production of weapons grade plutonium.

4.74 The Brisbane group, Citizens Concerned about Food Irradiation (CCFI) detailed the link between nuclear waste, caesium and the production of weapons grade plutonium. In summary CCFI argued that the logic of the United States Department of Energy (DOE) is to first create a caesium industry and the need for large amounts of the isotope to supply the sewage sludge, medical and food irradiation industries. Rather than create more cobalt 60 DOE will try to flood the market with cheap caesium which, using new technology, they can easily and cheaply extract from the spent reactor fuel. At the same time there will be plenty of weapons grade plutonium created for the government. These matters are referred to in paragraph 7.72.

4.75 One group argued that food irradiation has been judged wholesome and safe because of the overwhelming involvement of the nuclear industry which looks to food irradiation as a means of improving its public image and turning its nuclear waste dumps to profitable use.

4.76 Witnesses from ANSTO advised that they were concerned by some adverse statements tying together the use of ionising radiation for food treatment with the nuclear fuel cycle and even worse, with atomic weapons. Witnesses claimed that this was a totally unnecessary introduction of fear into the community. ANSTO advised that it is involved in an educational process providing information on the process, its advantages and disadvantages. The legislation establishing ANSTO requires it to:

- undertake research and development in relation to -
  - nuclear science and nuclear technology, and
  - the production and use of radioisotopes, and the use of isotopic techniques and nuclear radiation, for medicine, science, industry, commerce and agriculture;
- encourage and facilitate the application and utilisation of the results of such research and development, and
- act as a means of liaison between Australia and other countries in matters related to its activities.

4.77 ANSTO explained that power stations in Canada are producing cobalt not as part of the nuclear fuel cycle but as a deliberate process. Caesium 137 is attained by processing spent fuel rods. The US has small quantities of caesium 137 which are already committed. ANSTO believes that when this small stockpile has been utilised the cost of reprocessing fuel rods specifically to produce caesium for food irradiation will be too high. ANSTO believes that in the 1990's cobalt 60 will continue to be used.

4.78 The Committee accepts that if nuclear waste was processed to extract caesium, plutonium would also be produced. The Committee also received advice on some safety aspects of caesium, particularly its solubility and its relatively less penetrating gamma radiation. The Committee therefore concludes that the use of caesium is inappropriate as an irradiating source.

The Review Panels

4.79 Many of the submissions stated that the review panels failed to provide an independent and scientific assessment of the data because of vested interests of some of the members of these panels. The Committee was advised that the Chairman of the Burgen Committee was a part-time director of a major isotope manufacturer. In addition the technical adviser to the Burgen Committee was the Marketing Director and a leading shareholder in companies owning gamma radiation facilities. It was claimed that any decision in favour of food irradiation would directly benefit the two companies concerned. The obvious conflict of interest for key members of the Committee it was claimed severely undermines the credibility of their report.

4.80 The Committee noted however that the Burgen Committee had access to various expert panels with no direct association with the nuclear industry. The Committee has no means of assessing whether or not the findings of a Committee chaired by other than

Sir Arnold Burgen would have reached a different conclusion, but notes that the Burgen Committee's conclusions were consistent with other scientific panels.

4.81 The Food and Drug Administration has also been criticised. According to one witness the FDA during the 1970's was accused of sloppy, ineffective and even biased regulation of the drug industry. One explanation was because of the "revolving door" syndrome whereby top FDA personnel tend to be drawn from the drug industry and often returned to it. Also the FDA was criticised for relying on data collected by a company later convicted of conducting fraudulent research. This aspect is discussed in a later section of the report.

4.82 Again the Committee has no way of assessing the comments relating to the activities of the FDA in the 1970's. It notes however that the conclusions reached by the FDA are amongst the most conservative of all the scientific panels and assessments which were reviewed by the Committee.

4.83 Some witnesses observed that the Food and Agriculture Organization and the World Health Organization have been used by the International Atomic Energy Agency to lend some credibility to food irradiation. The European Parliament Committee on the Environment, Public Health and Consumer Protection stated that while advocates of food irradiation claim that WHO has confirmed that the technology is efficient, has no harmful effect on human health and can be used, WHO expressly stated that the Joint Expert Committee of which it was a member had not considered the general safety aspects of food irradiation.

4.84 One witness advised that approximately 20 years ago a section of FAO looking at agricultural uses of atomic energy merged with a section of IAEA which was examining a very similar proposition. It was claimed that the FAO/IAEA/WHO Joint Expert Committee was clearly formed to promote the use of atomic energy, particularly food irradiation.

4.85 The World Health Organization advised that the statement that it may have been deceived by forces promoting food irradiation lacks any basis and can only be understood to be an attempt to undermine its authority. WHO stated that it was satisfied regarding the safety of irradiating any food commodity up to an overall average dose of 10 kGy. The Food and Agriculture Organization and WHO commented that while food irradiation is not a panacea for all the numerous food supply problems in the world under certain circumstances it can be safely used to improve food safety and to reduce food losses. Both organizations were concerned that the unwarranted criticism of the process may hamper its use in those countries that may benefit most.

FDA/JECFI - Use of Data

4.86 The ACA Report suggests that the FDA and the 1980 JECFI meetings only examined 10 per cent of the available scientific material in common. This statement was based on a comparison of the FDA Bibliography of Toxicity studies on irradiated foods (15 September 1982 (including an addendum of 10 July 1985) and the collection of papers for the 1980 JECFI.[2] It appears that the Elias and Cohen material may have been only a small proportion of the material available to the JECFI meeting.

4.87 ANSTO advised that it has examined the FDA bibliography and other reference lists of materials used by the JECFI's, and has concluded that some 34 per cent (not 10) of the material used by the FDA is also known to have been used by the JECFI meetings.

References

4.88 A representative from the London Food Commission advised the Committee that he was gravely concerned that it was impossible to get some of these expert bodies to provide the kind of scientific references which would enable independent people to

check the findings of the committees. He was critical of the Burgen Committee and the World Health Organization which while providing bibliographies did not cite in detail the scientific data upon which they based their conclusions. The witness advised the Committee that it should request the World Health Organization to re-examine the question of food irradiation and provide a well referenced report. The National Coalition to Stop Food Irradiation and a Government Caucus Committee, for example, have called on the Australian Government to request the World Health Organization to re-open the investigation into the public safety aspects of irradiation and to produce a scientific factually referenced report on food safety, nutrition and the concealing of contamination in unsaleable food by irradiation.

4.89 While the references attached to the 1980 JECFI report may be limited, many references available to JECFI were published separately. In August 1981 IFIP published a table of toxicological studies carried out between 1976 and 1980. It contains over 140 papers which were available to JECFI. According to a member of the 1976 and 1980 JECFI's these studies were only the toxicological studies and do not include the microbiological, chemical and nutritional studies which were also available to JECFI. He advised that the programs of IFIP were documented in detail and were made available to the member countries of the international project and to WHO in over 60 technical reports and four activity reports. He believed that there would have been over 1000 documents available to JECFI and doubted the practicality of compiling these into a bibliography of limited value.[3]

4.90 A number of witnesses commented that it was difficult for them to obtain reference material to enable an assessment of the conclusions reached by various expert panels. One witness advised that he was unable to obtain many of the references to the CAST report. A library search indicated that the majority of these papers were held either at the ANSTO Library, the National Library or specialist scientific libraries. Another witness indicated that

he was unable to obtain some documents because of costs up to $900. These were the detailed reports of various toxicological studies some of which run to 15000 pages. The Committee notes that whilst it accepts that some witnesses may have had difficulty in obtaining the source documents most of the published papers which report the results of these studies are available in Australia.

International Consultative Group on Food Irradiation

4.91 Both the opponents and proponents of food irradiation agree that there may be widespread consumer resistance to the idea of eating food that has been deliberately exposed to radiation.

4.92 The Task Force on Marketing/Public Relations of Food Irradiation of the International Consultative Group on Food Irradiation has produced a working draft document on marketing and communication guidelines for acceptance and usage of food irradiation. The report states:

> "The initial marketing of food irradiation is not primarily aimed at consumers because its benefits are not immediately apparent to them. Consumers will not ask for food irradiation. They do not feel the need for it since they are not sufficiently aware of many of the present problems with food and the benefits the process offers. Marketing efforts aimed at consumer acceptance of food irradiation cannot be undertaken until regulatory authorities and interest groups acting on behalf of the consumer get food irradiation approved."

4.93 The report states that it is essential for communication activities to be structured as part of a deliberate well thought out plan. Major strategies are to:

. convince relevant government agencies;

- convince relevant non-government organisations;
- convince the food industry as a whole, and
- convince consumers.

4.94 The marketing report states that in many instances misinformation on irradiated food has created a confused, anxious climate of opinion which must be addressed by a communications plan. This approach was described by opponents of food irradiation as cynical and sinister. Witnesses advised that the so called "misinformation" is coming from highly reputable scientists whose views, because they contradict those of the proponents, are described as misinformation.

4.95 It was suggested that the government is the first target group because the public would assume that the government would not approve any dangerous food product. No reference is made to the need for a public debate with the consumer, particularly those who are opposed to the technology. The "questionable" but successful methods of the advertising agencies will be used to get around people's quite legitimate fears.

4.96 The marketing group clearly supports the use of a logo with no reference to the terminology "irradiation". It was suggested that this was a deliberate attempt to mislead the consumer.

Australian Nuclear Science and Technology Organisation

4.97 A number of witnesses were particularly critical of the role of ANSTO in the active promotion of food irradiation. While representatives of the then Australian Atomic Energy Commission may have been appearing as individual experts, resolutions and conclusions clearly indicate that their views were seen as views of the Australian Government.

4.98 ANSTO advised that with the explicit approval of the Australian Government it has at different times become involved in a number of international programs for the development of peaceful applications of nuclear energy. ANSTO argued that it has not been involved in the active promotion of food irradiation. ANSTO's expertise in the food irradiation field has been utilised through participation in international projects for the purpose of:

- assisting in the assessment of safety;
- determining optimum dose levels, and
- assessing the results of shipping trials.

It was not involved in the Task Force on Marketing/Public Relations of Food Irradiation.

4.99 Indeed the Committee was advised that ANSTO is required by its charter to encourage the development of nuclear technology for peaceful purposes.

National Health and Medical Research Council

4.100 The NH&MRC operates under a system of committees and sub-committees with particular areas of interest and expertise. These committees assess and make recommendations on submissions from individuals and companies for the use of a particular chemical or process.

4.101 The NH&MRC considerations and deliberations are conducted in private and are not subject to public submission or inquiry.

4.102 Many witnesses were extremely critical of the operations of the NH&MRC in the development of the Draft Food Irradiation Regulations. According to the Member for Hindmarsh the work of the Food Standards Committee (of the NH&MRC) moved along with little or no public input. It was claimed that this was clearly how those

in charge wished to proceed. Members of the Food Standards Committee were often given documents and submissions that were marked confidential. There was an air of secrecy surrounding the work of the Committee. He advised that the first public exposure of what the Food Standards Committee were up to in framing regulations was when he advised national newspapers in April 1986. Another witness commented that it may be reasonable to make minor changes in food regulations without wide consultation. Food irradiation however is different in that it is so pervasive. There was no consultation made with groups or individuals.

4.103 The NH&MRC advised that irradiation standards were dealt with and encountered in exactly the same way as other standards which go through the Committee. There was no difference whatsoever. The consideration of food irradiation was no more secret than consideration of any other aspect. Another witness from the NH&MRC advised that it recognised that it did not have a particularly high profile in areas of public health policy. To that end, the NH&MRC has established an Educational Publicity Committee for the purpose of ensuring that a broader cross-section of the community is aware of what is actually happening within the organisation. He further advised that in 1985 the NH&MRC informed the Press that it was considering the question of food irradiation.

4.104 The Committee notes that the procedures of the NH&MRC do not allow for sufficient public input into the decision-making process. This approach differs significantly from those in operation in Canada and the United States. The Canadian Department of Health and Welfare advised and sought submissions from the public to assist in its review of regulations relating to food irradiation. It is not clear whether or not this is a statutory requirement. The FDA has extensive notification and public input mechanisms. The Committee believes that similar provisions should apply to the NH&MRC particularly when matters

as contentious as food irradiation are involved. Accordingly the Committee recommends that:

> **the Minister for Community Services and Health, in consultation with State and Territory health Ministers, request the National Health and Medical Research Council to introduce administrative procedures enabling fuller public consultation and participation in the development of food standards regulations.**

4.105 The Member for Hindmarsh was highly critical of a working party set up by the NH&MRC to develop a public education program concerning food irradiation which had decided to proceed as a matter of urgency to put in place an education program and the publication of one million pamphlets. Questions in Parliament relating to its operation had remained unanswered and the views of consumer organisations had not been considered. The Member for Hindmarsh believed that it could only be concluded that the Committee was determined to get the information programmed "set in concrete" before having to answer questions relating to its activities. It was submitted that these matters of urgency were not in the consumers interest but were in the interest of the proponents of food irradiation. The material to be contained in the pamphlet provided only the proponents view of the process and could fairly be described as propaganda rather than information.

4.106 The Chairman of the Education Working Party did not accept these criticisms. He advised that he was not aware of the questions in Parliament and the "urgency" was to enable completion of the task. He accepted that some members of the working party were pro food irradiation.

Endnotes

1 Transcript p. 547.
2 Elias, P.S. & Cohen, A.J., "Recent Advances in Food Irradiation", 1983.
3 Diehl, J.F., Professor, Physiology of Nutrition Institute, FGR, Correspondence 10.5.1988.

5. FOOD SAFETY

Introduction

5.1 The safety of irradiated food has been the subject of considerable study for 40 years. These studies have included the chemical changes within foods and food components, *in vitro* experiments and *in vivo* studies involving various animal species, including humans. The majority of expert scientific evidence, both oral and written, which was considered by the Committee indicated that the process is wholesome and safe. There are some scientists however who argue that the results of some studies raise serious questions about safety and who question the quality and interpretation of many of the studies.

5.2 During the inquiry four main areas of concern emerged. These are:

- a general concern relating to the manner in which data has been assessed by scientific panels;
- products are formed which may be teratogenic, mutagenic or carcinogenic;
- irradiation may deplete food of essential nutrients which may have significant impacts on those on marginal diets or those who suffer from some form of allergy, as well as the effects on the immune response mechanisms, and
- the effects on micro-organisms including the enhancement of aflatoxin growth, radiation resistant bacteria and mutations.

5.3 The Committee believes that the burden of proof concerning safety of irradiated food rests with those who wish to introduce the process. It believes however that the proof required must be reasonable. The majority of the Committee has adopted the principle that the proponents of food irradiation must be able to demonstrate beyond all reasonable doubt that the process will not cause harm to those human populations to whom it is introduced. Other Committee Members however believe, in line with the advisers' conclusions contained in Appendix 4, that this might set too high a standard of proof and it is possible that the results of studies on any new process, drug or additive would have difficulty in achieving this standard. All Committee Members agree however that because some traditional food processes are known to cause harm to human populations it would be irresponsible to introduce a new food process without thorough investigation and analysis of possible adverse effects.

5.4 The Committee does however agree with the Australian Consumers' Association which concluded that no substance can be considered intrinsically one hundred per cent safe. Whether any substance produces harm depends on many factors such as the dose, the frequency of the dose, the living organism involved, the substance's interaction with other substances, environmental influences and the receiving organism's ability to counteract the toxic properties of the substance. Safety is always relative. Absolute safety is an unattainable ideal.

5.5 The Committee's evaluation involved:

- an examination of the general criticisms relating to the reviews of JECFI, FDA and other scientific panels;

- detailed reviews of some particular areas of concern, including polyploidy, aflatoxins and nutrition;

- assessment of the overall conclusion reached on safety and wholesomeness by scientific panels based on the Committee's own detailed examination of specific issues, and

- an examination of the concerns of some scientists and consumer groups that there is insufficient knowledge about the longterm effects of irradiated food on human health.

Toxicological Aspects

5.6 A government toxicologist advised the Committee that toxicology is a relatively new science and that it is not an exact science. Toxicologists require a broad knowledge of the biological sciences and few toxicologists could hope to gain sufficient knowledge in all these areas. As a consequence they rely heavily on expert advice. Decisions on toxicological issues require a great deal of judgement. This judgement, it was argued, needs to be exercised cautiously by persons experienced in the science who are in possession of all the relevant information. Another witness advised that further training was required in the field of human food toxicology.

5.7 The standard toxicological approach to test the safety of a substance is to feed the substance to a number of study animals at a range of concentrations and record the effect on the animals. The drug or food additive is fed at considerably higher concentrations than would normally occur in practice to find the maximum quantity which produces no observable effects and this quantity is then divided by a safety factor (commonly 100) to obtain a quantity allowable for humans.

5.8 The 1976 JEFCI and other scientific review panels observed that the approach needed in the toxicological evaluation of the wholesomeness of irradiated food differs from that used in

the safety evaluation of chemicals. It is impracticable to exaggerate the feeding levels of irradiated foods in animal studies beyond a modest degree, nor is it appropriate to exaggerate the radiation dosage much beyond that to be used in practice. These practices give rise to effects which are not relevant to the toxicological potential of the irradiated food. The evaluation of the wholesomeness of irradiated foods therefore poses problems of a different kind from those encountered with food additives or contaminants and it consequently requires a different approach. However one witness emphasised that in order to produce a measurable effect it was necessary to exaggerate irradiation doses to approximate the testing protocols for a drug or food additive.

5.9 The 1980 JECFI concluded that there is considerable evidence which exists to enable information obtained from toxicity tests on one irradiated food to be extrapolated to other foods of similar chemical composition. This assessment procedure is called the 'chemiclearance' method of evaluating radiolytic changes in irradiated food. This approach states that irradiation produces similar changes in foods of similar types which means that tests are not required on a whole class of foods (e.g. cereals) if a member of the class has already been tested (e.g. wheat). The chemiclearance approach is a chemical approach and is not based on feeding experiments. Its basis is theoretical rather than practical in that it looks at <u>in vitro</u> experiments rather than <u>in vivo</u>.

5.10 A Reader in Physical Chemistry did not completely agree that the chemiclearance method could be used in all instances. He advised "if the method shows up zero" then the approach may be appropriate. He advised however that "if it shows up anything" then each food should be examined individually.

5.11 A Sydney group, People Against Food Irradiation, advised the Committee that a review of animal feeding experiments from

1925 to 1976 undertaken for the International Food Irradiation Project found that after looking at 959 studies of 186 different foods and feeds that neither beneficial nor detrimental effects of irradiated food consumption are consistent, unambiguous and reproduceable. Neither can specific effects be related to a given food, group of foods or level of radiation dose. The witness questioned the validity of the chemiclearance method of evaluating irradiated food since it relies absolutely on factors which the review concluded are unpredictable. In other words chemiclearance relies on effects being able to be related to a given food, group of foods or level of radiation, the opposite to what was found in the review.

5.12 The IFIP review found that many early animal tests were invalid because the diet provided was nutritionally inadequate, due to the high percentage of food in the diet that was unnatural for the animal or due to nutrient destruction after very high doses of irradiation. In addition many of the studies indicated that irradiated food showed somewhat greater signs of toxicity than the unirradiated food, and many studies indicated the reverse.

5.13 The New Zealand Institute of Nuclear Science argued that if the toxicity of the irradiated and unirradiated food are, in fact, identical and that a large number of different tests are performed comparing the two it would be expected that:

. the results of the 2 groups will rarely be identical;

. roughly 50 per cent will indicate that the irradiated food was slightly more toxic and 50 per cent will indicate the unirradiated food was slightly more toxic; and

. if enough tests are done then there will be an occasional result in which the greater toxicity of one or the other appears large enough to be significant.

5.14 The Institute concluded that this was basically what was observed by the IFIP review. The distribution of positive and negative results is what would be expected if there is little or no difference in the toxicity of irradiated and unirradiated food.[1]

5.15 Many witnesses claimed that the inadequacy and conflicting results of previous studies is illustrated by the fact that the FDA found only five adequate. The FDA commented that although most of the studies it reviewed were inadequate by present day standards and could not stand alone to support safety, many contained individual components that when examined either in isolation or collectively support the conclusion that the consumption of foods treated with low levels of irradiation does not cause toxicological effects. Further the FDA found that many of the studies were useful in resolving questions about the effects of irradiation. The FDA reviewers did find 5 of the studies they reviewed were properly conducted and fully adequate by 1980 toxicological standards and able to stand alone in support of safety. According to the FDA reports these 5 studies did not reveal any adverse effects from the irradiated foods fed to test animals.

5.16 The Chairman of the Department of Preventative Medicine and Community Health, New Jersey Medical School,[2] in written and video tape submissions to the Committee, stated that the FDA approval appeared to be based on only 5 or 6 studies on rats and dogs. He observed that given that only a small number of studies were considered adequate those selected supposedly were virtually impeccable studies. He identified problems with all of the studies and advised that taken together these studies could not possibly establish the safety of food irradiation. The submissions advised that two of the five animal feeding studies which the FDA deemed acceptable on 1980 standards were reviewed by five epidemiologists and biostatisticians who found substantial problems in their

interpretation. For example in the case of one study it was claimed that rats fed on wheat which had been irradiated at 2 kGy showed a significant increase in the rate of stillbirths.

5.17 The FDA advised the Committee that the submissions seriously misrepresent the basis for the FDA's decision on the safety of irradiated foods. In reaching its decision the FDA stated that it comprehensively reviewed data on the chemistry of food irradiation and all available studies on possible toxicity of irradiated foods and irradiated food components. The FDA also carefully considered the effects of irradiation on nutrients and micro-organisms. The FDA concluded that the irradiation of any foods at doses below 1 kGy and the irradiation of minor dry ingredients at doses below 30 kGy would have no adverse effect on the safety of the foods.[3]

5.18 The FDA found that animal feeding studies should not be required to demonstrate the safety of foods irradiated at low doses because the effect on food under these irradiation conditions is so small. Nevertheless the FDA carefully evaluated all data from such studies. The FDA found that readily available information on many animal feeding studies was incomplete. Also, many of the older studies do not meet all the design standards that would be applied today. In 1982, an FDA Task Force concluded that, except for a few studies, the animal feeding studies available did not meet 1980 design and reporting standards. The Task Force noted, however, that none of the studies they reviewed showed adverse toxic effects and, in particular, the few studies meeting the standards which would be applied today all demonstrate that the foods tested were safe. These latter few studies meeting today's standards appear to be the 5 or 6 studies discussed in the submissions.

5.19 In terms of the other criticism the FDA replied that no calculations were provided to support the claim about the increased rate of stillbirths. The FDA accepted the study's

conclusions that the pattern of mortality was not consistent with an adverse effect of consuming irradiated food and the mortality for all groups was within the normal range for this rat colony.

5.20 The FDA reached the conclusion that food irradiation, on the whole, was safe up to a maximum dose of 1 kGy (30 kGy for spices). JECFI concluded that irradiation was safe to an average dose of 10 kGy. The Committee was advised that it was apparent, that while there are differences, the points of similarity are that most of the individual findings suggesting potential toxicological problems with irradiated foods have been evaluated and rejected as of no concern. Both bodies considered that there was no substantive evidence that food irradiation may cause toxicological harm on the basis of the overall data presently available.

5.21 The agencies differ on the weight which can be given to the overall toxicity data. JECFI believe that no further toxicological testing is warranted up to a dose of 10 kGy. FDA believed that the database was inadequate to support a broad decision that all foods may be safely irradiated at higher doses than 1 kGy.

5.22 A past member of JECFI advised that the FDA, like regulatory authorities in other countries, was responsible for translating general recommendations by expert committees into a practical regulatory framework responsive to the needs and interests of the community it serves. The Committee was also advised that the difference may be due to the classification of irradiation sources as a food additive in US legislation. For doses below 1 kGy the FDA could use arguments based on radiation chemistry and the power of animal testing to show that irradiated and unirradiated food would be indistinguishable toxicologically. Therefore, animal testing was unwarranted. Above 1 kGy the FDA could not be sure that they would be indistinguishable. The FDA is then mandated to require not only toxicological tests, but to

apply criteria developed as modern, rigorous tests suitable for animal testing of food additives. These appear to include sufficient single large-scale studies each 'capable of standing alone in support of safety'. The tests have strict rules governing the type and breeding of test animals, the statistical tests applied and, in particular, rules on the animal diets and the need to feed additives over a wide dose range.

Relevance of Animal Studies

5.23 The relevance of animal feed studies to assess safety in humans was raised by a number of witnesses, particularly whether the observations in non-human systems can be used to assess safety in human systems.

5.24 Numerous direct feeding studies have been conducted during the past 35 years to assess the wholesomeness of food processed with ionising energy. Some have been large-scale experiments. Lifetime studies have been carried out with animals (including four generations of rodents). Assessments have been made of possible relationships between the consumption of foods processed with ionising energy, and the development of cancers, birth defects and genetic changes. It is argued that the results have provided no confirmed evidence that processing food with ionising energy creates these or other toxicological hazards.

5.25 In addition animal colonies at research institutes worldwide have been raised on irradiation sterilised diets supplemented by vitamins. At the Walter and Eliza Hall Institute of Medical Research, for instance, laboratory mice have been bred exclusively on food sterilised by gamma irradiation since 1961 for 61 generations. At least 2.4 million mice have been born to parents receiving an irradiated diet. No teratogenic or oncological effects have been observed which could be attributed to the gamma irradiation of the diet. Life span was not monitored nor were detailed biochemical examinations undertaken as these

were not formally designed scientific experiments. It was stated however that if adverse effects had been observed by researchers using these mice in experiments such effects would have been reported. An immunologist advised that the animals which had been raised on irradiated food seemed to have normal immune response mechanisms.

5.26 It was argued that these sorts of studies can provide information of only limited value about carcinogenicity, teratogenicity and mutagenicity. Human nutritional needs and digestive systems are not the same as experimental animals. Limited short term studies using human subjects have been undertaken in the US, India and China and hospital patients have been fed irradiated diets in a number of countries. It was argued that the kind of epidemiological study required to find out whether or not a diet of irradiated food will increase the frequency of cancer or genetic injuries among humans has not been done. Such a study would require controlling the diets of at least 200 000 humans of various age groups for at least 30 years and following their health histories for at least 30 years.

5.27 A biochemist, in an article, commented that extrapolation of risk from rodents to humans is difficult for many reasons, including the longevity difference, anti-oxidant factors and the probable multicausal nature of most human cancer.[4] Other witnesses advised that in the long term safety can only be determined when human beings are involved.

5.28 A medical researcher commented that the best animal tests are "extremely blunt" in picking up the incidence of cancer. He described two substances, notably benzene and arsenic, which are not cancer causing in animals even though they are in humans. He believed that there could be a low to moderate level of risk which would not be identified in crude animal tests.

5.29 The United Kingdom Burgen Committee, which supported the introduction of food irradiation, concluded that if it was agreed that food irradiation should be permitted in the United Kingdom procedures should be established to monitor the consumption pattern of irradiated foods and their nutrient content to detect any unforeseen nutritional consequences. There would equally be a need to review new toxicological data on irradiated foods and to consider any toxicological implications of new applications of food irradiation, which might be revealed by monitoring the extent and pattern of its use. The British Medical Association believed that because of the lack of scientific data such studies should be undertaken in those countries where the process was already in use before the process could be confidently accepted in the United Kingdom.

5.30 The United States Food and Drug Administration in responding to the request for long term human feeding studies commented that it has never required such long term testing in humans to approve the use of a food additive and did not agree that such a study is necessary or appropriate. The FDA recognised that it could not say with absolute certainty that any food, irradiated or not, is absolutely safe for all people under all conditions. The FDA believed that the differences between foods irradiated, as prescribed by their regulations, and non-irradiated foods were so small, particularly compared to normal variations in the diet, that no effect would be expected to be observed.

5.31 The FDA believed that the substantial amount of available toxicological information supported the conclusion that the irradiation of food was safe. Therefore there was no basis for delaying for decades a decision to regulate food irradiation in order to conduct the type of study suggested by these comments.

5.32 One witness stated that if food irradiation was adopted before adequate evaluation of adverse effects is performed so many

people would be exposed to it that it would be virtually impossible to conduct proper epidemiological studies on adverse effects because it would be impossible to find an appropriate unexposed population to use as controls.[5]

5.33 While toxicologists recognise there are important differences between humans and other animals the Committee was advised that the major organ systems within mammals are very similar. Scientists have shown that biological pathways in certain animals are identical to humans or correspond closely enough to humans for them to be acceptable scientifically and allow the interpretation of one result to another. It is essential however that the appropriate animal model is used. The limitations of data might be that if a chemical causes damage in one mammalian species it is very likely that it will cause it in another species, but it is not possible to determine at what dose levels that may occur.

5.34 Animal studies are generally accepted as the only practical way of evaluating the safety of a wide range of chemicals and processes and at least one witness believed that there is very little evidence that animal studies have failed. While thalidomide is given as an example as a tragic failure of animal testing and therefore care should be used in using the data it is clear from the evidence presented to the Committee that if the trials on thalidomide had been conducted properly tests on animals would have clearly indicated an adverse effect on the foetus. In fact because the drug has adverse effects on animals it is often used as a control in studies testing new drugs for possible birth defects.

Data Credibility

Industrial Biotest Laboratories

5.35 Witnesses commented that the credibility of the research supporting food irradiation is now in question because many of the

studies were performed by Industrial Biotest Laboratories (IBT) of the United States. In 1983 IBT officials were found guilty in a federal court of defrauding the Government in safety tests of other drugs and chemicals. Investigations revealed failure to conduct routine analysis, premature death of thousands of rodents, faulty record keeping and suppression of unfavourable findings. The FDA agreed that studies containing falsified data performed by IBT should be rejected. All studies identified in the FDA's review of available toxicological literature on food irradiation that had been performed by IBT were rejected.

5.36 Doubts have been cast on the analysis and conclusions drawn by the 1980 JECFI. Tests were performed by IBT which found no toxicological problems with irradiated cod, redfish, papaya, strawberries, apples and pears. IBT was contracted by the International Food Irradiation Project (which co-ordinated the safety data supplied to JECFI) to perform the work on cod and redfish. While JECFI declared the wholesomeness of irradiated fish partly on the results of these IBT cod and redfish studies information available to the Committee indicates that results from other laboratories were available to JECFI on fish and fish products.

Vitamin Supplementation

5.37 It was argued that many of the animal feed trials are invalid because vitamin and other supplements had been used to mask the adverse effects of irradiated food.[6]

5.38 It is clear that vitamin and other supplements were added to experimental diets. The 1964 JECFI commented that since the animal studies were intended to detect toxicity and carcinogenicity rather than the destruction of essential nutrients at least a minimal requirement of essential nutrients should be provided from the non-irradiated components of the diet. The nutritional quality of the diet should be adequate to ensure

normal growth, reproduction and life span in the species used. On the other hand JECFI observed it would be unwise to include excessive quantities of essential nutrients in the ration since this could mask the presence of antimetabolites possibly formed during irradiation of the test food.

5.39 The vitamin supplements are invariably vitamins E and A. It was argued that rather than supply vitamin supplements to avoid a deficiency, in actual fact huge amounts of vitamins were supplied to suppress the effects of irradiated food. It was similarly argued that it was not possible to draw conclusions from animal colonies bred on irradiated food because of the dietary supplements. A witness from the Walter and Eliza Hall Institute advised that their animals are receiving more than their recommended daily allowance (RDA).

5.40 One conclusion drawn was that weekly supplements, particularly of vitamins E and A, successfully suppress adverse effects. Other research without the use of extra weekly vitamin supplementation indicated a wide variety of adverse effects. Therefore the feeding experiments by the promotors of food irradiation were claimed to be fraudulent.[7]

5.41 The Committee was advised that two of the animal studies used by the FDA very specifically highlight the food nutrition issue. In the 1964 report in Food and Cosmetic Toxicology, the authors noted that both the control animals and those fed irradiated wheat were given supplementary vitamins; in part, "this was done to avoid the reproductive difficulties that were attributed to destruction of vitamin E induced by radiation". In the German experiment, in the first year of analysis those animals given irradiated foods weighed significantly less than control animals and showed reproductive defects; both these abnormalities were corrected by administration of vitamins, particularly vitamin E.[8]

5.42 The FDA noted that it was not claimed that these studies showed toxic effects. The FDA believed that the point concerning nutrient losses is based on isolated facts taken out of context. The FDA stated that one must recognize that any type of food processing will affect nutrient value, but such losses are not necessarily of any nutritional significance. In the studies cited, very high sterilising doses were used for a major portion of the diet and precautions were not taken to preserve nutrients during processing. Because the studies were designed to detect possible toxic (not nutritional) effects, and because the irradiated food constituted such a large fraction of the diet, supplementary vitamins were added to prevent nutritional artifacts from confounding the study. The FDA claimed that this is proper science in that the scientists were controlling the variables to allow proper interpretation of the results. The FDA recognised, however, that irradiation processing may not be suitable for all foods. The FDA advised that it only permits irradiation under conditions where nutritional effects are insignificant.[9]

5.43 The Committee was advised that the addition of vitamin supplements did not make the studies invalid. The Committee was also advised that vitamin supplements were added to experimental diets in some studies which had indicated adverse effects, therefore there was an inconsistency in the argument.

5.44 The Committee's advisers believe that the fraud hypothesis requires that a number of assumptions need to be made. These are:

i. That large amounts of potentially genotoxic radiolytic products are generated in food irradiated at doses of less than 10 kGy (for human consumption) or greater than 10 kGy (for animal experiments). The advisers were not satisfied with this assumption, especially for the lower dose levels.

ii. That these radiolytic products persist in large amounts for relatively long periods of time. The Committee received evidence that most such products are unstable and short-lived. It notes also that very similar chemicals are found in foods treated in a wide variety of ways other than radiation and also in normal human cells and tissues.

iii. That when fed to animals, relatively large amounts of these radiolytic products are transferred from food to the animals themselves, in such a way that they can reach the genetic material of certain cells and cause damage to that genetic material. The Committee's advisers consider that no persuasive evidence exists to indicate that this process occurs.

iv. That when certain vitamins (notably A and E) are present in large quantities, the postulated effects on cellular genetic material can be prevented or at least reduced (this is usually referred to as "suppressing the effects of irradiated foods"). Given that i., ii. and iii. above are not found to be reasonable by the advisers, in their opinion iv. can be seen as of little if any relevance to the issue of the safety of irradiated food.

5.45 Specifically for humans, the advisers consider a further assumption would have to be made:

v. That people who eat irradiated food as part of their diet will somehow become vitamin deficient and hence at increased risk of suffering damage to their genetic material which could lead to mutations or cancer. If i. and iv. above were to be accepted, the "key" vitamins A and E would still be present in the diet as a result of other dietary components (as well as the substantial proportion which is retained in foods irradiated at doses of up to 10 kGy).

5.46 The Committee concludes that the experiments and studies undertaken which included vitamin supplements are not fraudulent because of this supplementation.

Induced Radioactivity

5.47 There was general agreement that ionising radiation produced by cobalt 60, caesium 137, x-ray machines and electron beam machines in facilities operated at the recommended levels does not induce any measurable increase in radioactivity over and above that naturally present in foods and other products. The evidence clearly shows that the differences in natural radioactivity between different non-irradiated foods are greater than any difference between the same irradiated and non-irradiated product. Even those concerned with the introduction of food irradiation accept that properly controlled irradiation should not make food radioactive.

5.48 This view, however is not held by all those who appeared before the Committee. In a major submission presented by the Citizehs Concerned about Food Irradiation it was argued that while a photon to neutron reaction cannot occur at the energy levels of cobalt or caesium or at the allowed levels of x-ray or electron machines, isomer activation can occur at low energy levels. Isomer activation occurs when a photon is absorbed by a nucleus with the prompt emission of a second photon of lower energy. The witness argued that these metastable nuclear isomers were induced radioactivity and gave rise to the polyploidy which was observed in animal and human cells following the ingestion of irradiated grain.

5.49 The Committee was advised that isomer activity has not been detected in foods even from irradiation with high energy electrons.[10] The CCFI witness claimed that all that this indicates is that biological detection methods are far more sensitive than

machines. Advice received by the Committee however indicates that simple hand held radiation monitors can easily detect levels of less than 1 microgray per hour. The lower limit for direct biological monitoring by measuring chromosomal damage is at best about 0.1 Gray. In addition the natural background radiation including radioactive substances in food would have an effect many millions of times more than that of nuclear isomers if they did exist in irradiated food. Two cytogeneticists advised that there is no evidence or suggestion from the studies that freshly irradiated wheat produces any chromosome damage of the type usually attributed to radiation.

5.50 If the polyploid cells were the result of induced radioactivity the radiation levels induced in medical products sterilized at higher doses would be such that they would be very radioactive, so much so that they would give high radiation doses to people handling the sterilised goods. Film badge records show that this is not so.

5.51 The Committee accepts that induced radioactivity at the recommended energy levels, even if it were to exist, would not pose a health risk.

Radiolytic Products

5.52 The irradiation process causes the production of highly reactive free radicals which readily react with adjacent molecules and result in the formation of numerous radiolytic products in the food. The debate about free radicals and other radiolytic products centres on three issues, namely that:

. the products are formed in quantities which may be harmful to humans;

- the products formed may be 'unique' in the sense that they are different from products either found naturally in the food or formed upon processing food by other methods or else formed by oxidative events in human cells, and

- some have yet to be identified.

5.53 Research on radiolytic products has been carried out for more than 30 years to discover their nature, the amounts formed and their relation to the nature of the food, the amount and form of ionising energy absorbed and the effect of conditions of processing. Much of this research has been conducted at very high dose levels, levels far higher than would be used in commercial practice.

5.54 The United States Council for Agricultural Science and Technology report outlines the conclusions reached by extensive assessment of the research data relating to formation of radiolytic products at commercial doses. The CAST report concludes that all of the known radiolytic products derived from major food components are found in unprocessed foods or in foods subjected to other accepted types of processing, such as cooking.

5.55 Various authorities to date have not dismissed the possibility that unique and potentially toxic substances may be formed.

5.56 An advisory panel to the United Kingdom Burgen Committee examined data relating to the toxicity of chemicals in food and the chemical changes which occur in food as a result of irradiation compared with the changes occurring as a result of other accepted methods of food processing. The other processes considered were storage, cooking, freezing, drying, smoking, fermentation and treatment with sulphating agents, nitrite,

nitrate, ethylene dibromide and ethylene oxide. The panel advised that most of the known radiolytic products of foods were either found naturally or were formed as a result of other methods of preservation. The panel commented however that it was noted that a few of the products formed in irradiated food are not formed as a result of other food processing methods. The panel concluded that there is no evidence that these compounds are toxic.

5.57 ANSTO argued that there is unchallenged evidence that several grams of naturally occurring toxic substances, mutagens, teratogens and carcinogens from both fresh and cooked foods are ingested by humans. Nevertheless ANSTO argued these compounds are not harmful to humans or animals because they are rendered harmless by efficient bio-chemical mechanisms.

5.58 If minute quantities of 'new' chemicals are present in foods after irradiation ANSTO argued that it would be logical and consistent to presume they are similarly detoxified. Numerous animal feeding trials and specialised <u>in vivo</u> genotoxic tests involving a wide variety of foods have failed to detect adverse effects. ANSTO believes that the occasional reports of adverse effects which have appeared in the literature have either not been confirmed on re-investigation or can be shown to have no statistical significance.

5.59 Witnesses from the Commonwealth Scientific and Industrial Research Organisation Division of Human Nutrition advised that the supposition of those opposed to food irradiation is that there are no mechanisms within the human body which can deal with products which have been shown to be harmful, such as peroxides and free oxygen radicals. The witness advised that these occur normally in the body as a result of the body's own machinery, its own enzymes, its own processing of energy. There are excellent mechanisms in each cell which mop up these free oxygen radicals and neutralise the peroxides. The witness concluded that he found it extremely unlikely that ingesting the

products of these chemical processes is likely to be harmful when the body generates exactly the same chemical processes all the time within every cell and has the capacity to neutralise exactly those self same products.

5.60 The Committee's advisers believe that the claim that the consumption of irradiated food causes genetic damage makes a number of doubtful assumptions. It assumes that irradiation produces genotoxic radiolytic products in food which persist long enough to be absorbed in sufficient quantity by the organism to then reach the DNA in the cell nucleus in their genotoxic form. It further assumes that any genetic damage that these products cause in the DNA of exposed cells is converted to fixed mutations, and any such cells either become cancerous, or else, because the changes in the DNA occur in germ line cells, are then transmitted to the next or subsequent generations.

5.61 According to the advisers the major implausibilities with this punative causal chain are that: radiolytic changes in food produced by irradiation occur in extremely small quantities; these products have very short half-lives; they occur in much larger quantities in other food; they are produced endogenously in body cells as part of normal metabolic processes; and, most importantly, all aerobic cells have had to evolve mechanisms for dealing with such products.

5.62 The radiolytic products about which opponents of food irradiation appear to be most concerned are hydrogen peroxide, superoxide radicals, and oxygen radicals, and some of their reaction products, such as hydroperoxides, endoperoxides, and fatty acid peroxides.

5.63 The Committee was advised that all of these chemicals are present in a wide variety of foods at significantly higher concentrations than those additional ones which are produced by food irradiation using the relatively low doses (less than 10

kGy) which are likely to be used in practice. More importantly, hydrogen peroxide and superoxide are continuously generated within human cells and subcellular organelles (e.g. peroxisomes) as a side-product of cell metabolism. These molecules are the major sources of oxygen radicals within the bodies of animals and humans.

5.64 One of the important bodily defenses against bacterial infection is a high level oxygen radical burst following phagocytosis (cellular entrapment) of certain types of potentially harmful bacteria. The oxygen radicals kill the bacteria but not the human cells in which they are generated, clearly indicating that human cells have a significant capacity for defence against the oxygen radicals which they themselves necessarily produce. Because animal metabolism is basically an oxidative process, the generation of the inorganic molecules is an essential feature of life. All aerobic organisms have accordingly evolved strategies for coping with the potential harm to the genetic material that constant exposure to oxygen radicals may pose.

5.65 It is the advisers' view that interactions between oxidative radicals, for example, and the organic molecules which might be expected to occur in irradiated food are found both in food treated in other ways, and in the cells of living animals. Many enzymes protect cells from oxidative damage, examples including superoxide dismutase, glutathione peroxidase and the glutathione transferases. Such enzymes have to be present in all organisms which depend on oxygen for their existence in order to deal with oxidative damage, as indeed do enzymes necessary to remove the oxidative damage from DNA which also occurs on a regular basis.

5.66 The advisers commented that the conventional argument that we cannot rely on information obtained in animal experiments to provide information about the effects of irradiated food on

humans has much less validity than may be the case for other types of chemicals. This is so for the reasons outlined, namely, oxidative damage is universal, it is caused by the secondary effects of simple inorganic molecules rather than by novel man-made chemicals, and all cells have evolved mechanisms to protect DNA from internally generated oxygen radicals.

5.67 Given the 24 hour-a-day production of significant amounts of oxygen radicals and other oxidative species within humans and other animals, the advisers concluded that it is extremely implausible that the minute additional contribution which might be made by consuming irradiated food could significantly alter the course of the natural events in living cells, especially at the genetic level. They further concluded that for all these reasons, the fact that no reproducible adverse effect of consuming irradiated food appear to have been found over many years of experimentation is entirely consistent with what is known about the chemical changes which result from food irradiation.

5.68 A Professor of Medicine with expertise in nutrition advised that with pharmaceutical products, for instance, many have some kind of analogue in nature. What is not known however is whether an entirely novel radiolytic compound may encounter the metabolic apparatus that is able to detoxify it. He thought that most of them would be but he did not think that it could be presumed that that necessarily follows for all radiolytic products.

5.69 The Food and Drug Administration addressed the question of radiolytic products such as the probability that a toxic radiolytic end product may be formed and whether or not a product would be present in sufficient amounts to make the food unsafe. The FDA stated it had no evidence to reach this conclusion at the doses allowed by its regulations. The FDA further concluded that the creation of free radicals would not be a problem as the high

water content of all fresh food provides a medium for their rapid degradation after irradiation, thus they are not likely to persist or be present at all in food by the time that food reaches the consumer. Their view was that even with dry foods such as spices where free radicals may persist over time as ingredients in other foods that contain water, the added water provides a means for rapid degradation.

5.70 The FDA also addressed the question of unique radiolytic products and agreed that some radiolytic products assumed to be unique may well be natural or common components undetected in non-irradiated food. The FDA concluded however that it is impossible to demonstrate with absolute certainty that this will always be the case for all radiolytic products.

5.71 The Committee accepts however that because quantities of radiolytic products formed are small this does not necessarily indicate that they will have no adverse effects. A number of witnesses indicated that effects can be observed for some chemicals at levels of parts per billion or trillion (e.g. dioxins, LSD).[11] The Committee understands that radiolytic products yet to be identified in foods would be of this order of magnitude. The Committee was advised however that if products were created in irradiated foods which were as potent as dioxins or LSD their effects should have been observed in the animal feed trials and the various in vitro tests.

5.72 The Committee is satisfied that many of the products formed in irradiated food occur naturally or are created by other forms of processing and that many are shortlived. It accepts expert evidence that most of these would not cause harm. As discussed previously the Committee's advisers consider that eating irradiated food is unlikely to have adverse effects as a result of the radiolytic products formed in the food because the body generates similar products as part of normal cell metabolism. It notes however that other reputable authorities

have indicated that it would be inappropriate to assume that all products formed would not be harmful or that they could readily be detoxified by human biochemical mechanisms. The Committee concludes in a later section of the report that if food irradiation were to be introduced then the consumption patterns be monitored and health effects be assessed. It believes however that before human populations are exposed to irradiated products a review of existing data should be undertaken and that new studies be conducted in non-human species where data is lacking. The Committee is not satisfied that all earlier animal feed trials are of a standard that would be accepted at the present time to indicate safety or otherwise of a new drug or process. The Committee's view coincides with that of the FDA which could find only five studies which satisfied 1980 toxicological standards. The Committee notes the views of its advisers concerning oxidative damage and considers that the scientific evidence relating to this view should be examined as part of the review recommended in paragraph 5.143.

Fats

5.73 ' Some submissions were concerned about the formation of carcinogenic and mutagenic substances in irradiated fats.[12] It was stated that studies indicated that the irradiation of foods which contain unsaturated fats result in a many times increase in the known carcinogens, the benzopyrene quinones. The submissions which commented on fat refer specifically to a 1986 study which indicated that fish oils and fatty fish irradiated in air induced peroxidisation of unsaturated fats and the formation of products with mutagenic and toxic activities. Benzopyrene (BP) is present in small quantities (parts per billion) in many foodstuffs, particularly smoked and barbequed foods, and although not itself carcinogenic it is converted in the body to oxygenated products such as quinones which have mutagenic and carcinogenic activity when measured by external tests.

5.74 Advice received from ANSTO indicated that the study has little relevance to normal commercial practices. ANSTO advised that BP detected in smoked foods range from less than 0.1 to 60 parts per billion with a typical value of less than 10. The level used in the experiments was over 9 000 parts per billion. ANSTO also commented that in normal practice it is unlikely that high fat foods will be irradiated. Various animal feeding experiments failed to show any abnormal reactions or toxic symptoms. Some experiments using doses as high as 100 kGy with polyunsaturated fats constituting 20 per cent of the diet showed no evidence of toxicity.

5.75 A paper submitted to the Committee concluded that in view of the limited value of irradiating highly unsaturated fatty foods, the likely lack of extra peroxidation in complex foods containing anti-oxidants, the occurrence of natural peroxidation and the natural metabolic oxidation of potential hydrocarbon contaminants, peroxidation does not seem a reason for great concern. However it would be advisable to seek information on the extent of peroxidation likely if any serious proposal was made to irradiate highly polyunsaturated foods.[13]

5.76 Based on evidence received during the inquiry the Committee in a previous paragraph expressed its reservations about many of the earlier feed trials. It believes that the effects of irradiating fats should be examined as part of the review recommended in paragraph 5.143.

Sugars

5.77 Submissions to the FDA and to the Committee objected to the approval of the irradiation of any fruit or vegetable because of reports that irradiated sucrose solutions caused toxic effects. A submission to the Committee advised that there are studies which show that irradiated sugar produces formaldehyde. Irradiation of only 30 milligrams of sucrose produces a mutagenic

dose of formaldehyde. The submission concluded that since carbohydrate was ubiquitous in foods it was likely that the most prevalent radiolytic product would be formaldehyde.[14]

5.78 The FDA concluded that in feeding studies where sugars were present in a typically complex food matrix, there was no increase in mutagenicity after irradiation. Irradiation of a whole fruit demonstrated that when a food containing sugars was irradiated the food does not produce the same toxic effects that occur when the sugars were irradiated in simple solution.

5.79 The Committee believes that these issues should be re-examined as part of the World Health Organization review.

Microbiological Hazards

5.80 A number of witnesses referred to the possibility of mutant strains of organisms developing in irradiated foods. These strains may be more pathogenic, more radiation resistant and/or more difficult to identify or detect. It was argued this was even more possible in the case where products were irradiated more than once.[15]

5.81 There are two means by which radiation resistant bacteria may occur, that is, through selection or mutation. In the case in which survivors of an irradiation process are more radiation resistant irradiation can become a procedure for selectively favouring such naturally resistant bacteria. Alternatively, enhanced radiation resistance may be acquired by radiation induced mutation of the original bacteria. Mutation of bacteria has been observed but only with repeated radiation through several life cycles.

5.82 ANSTO advised it was quite difficult to use irradiation to make bacteria more radiation resistant because one has to irradiate and look at the survivors, grow them in another living

culture and irradiate them again and continue the process for several cycles. ANSTO doubted that in a practical commercial situation this would happen. ANSTO has conducted research on a number of mediums and has not discovered any virulent radiation resistant micro-organisms. Overseas studies showed that in the case of salmonella, for example, no immunity appeared at all until after 10 doses of irradiation.

5.83 An adviser to the ACA and a witness before the Committee's inquiry stated that most of the mutations induced by irradiation are disadvantageous to the bacterial species themselves. On the whole mutants do not tend to survive. The report also comments that with viruses most mutations do not lead to better surviving mutants.

5.84 In a detailed paper presented on behalf of CCFI the conclusion was reached that it will be only a matter of time before radiation resistant bacteria are common in and around irradiation plants. One microbiologist argued that it is "really very extraordinarily unlikely" that radiation resistant mutants would proliferate and argued further that "indeed the fact that they will take over is again almost certainly totally erroneous".[16] He believed that the effect of food irradiation on the genetics of bacteria as far as the normal world was concerned was really irrelevant.

5.85 The Food and Drug Administration also addressed the problem of the production of potentially harmful radiation resistant bacteria, new bacteria or viral mutagens. The FDA commented that mutants produced during irradiation of food are essentially the same as those that occur naturally. The only real difference is in the rate at which mutations occur. Nor is there any reason to expect that the resulting mutants would be different or more virulent than those created by nature.

5.86 A related concern was that consumers rely upon the appearance, smell and texture of food for warning signals of contamination. Spoilage organisms play an essential role in this process. Commercial doses are not adequate to sterilise food but will reduce the microbial population and possibly kill the less harmful micro-organisms while not affecting the more harmful micro-organisms such as those which produce toxins and cause botulism. It was argued that botulism toxin will be produced before the spoilage characteristics are formed which would otherwise prevent the consumption of the food. It is argued that this would particularly occur in irradiated fish. ANSTO concluded that the risk, if any, is very low.

5.87 Generally the toxin is formed at temperatures above 10°C and consequently cause no hazard for products that are refrigerated. One type which can be found in fish, on the other hand, can produce toxin at temperatures as low as 3°C. Factors which affect the relationship between product life and toxin formation include dose, temperature of storage, level of spore contamination, species of animal food and possibly packaging. The use of a dose sufficient to secure a large extension of product life can lead to toxin formation within the period of the product life, provided other factors such as storage temperature permit toxin formation. One witness advised that a similar result could occur with traditional technologies such as pasteurisation by heat and even untreated vacuum packed fish.

5.88 Each of the following two conditions appear to be generally regarded as providing safe fish products. First, restriction of irradiation to products secured in locations that have been demonstrated to be free of contamination by the botulism causing organisms and secondly the handling of the product post irradiation at temperatures below 3.3°C. A number of authorities point out however that there is no record of botulism poisoning where a product has been cooked before consumption. Cooking causes inactivation of any toxin present.

5.89 The Food and Drug Administration agreed that this was a legitimate concern in some situations but argued that it does not apply to irradiation of dry foods or foods irradiated below 1 kGy. Irradiation of foods below 1 kGy will destroy few spoilage bacteria and thus will not change normal spoilage patterns. The US Food Safety and Inspection Service has prohibited the sale of irradiated vacuum packed pork because it believes insufficient data exists on botulism.

5.90 The Committee notes the conclusion of the ACA that fish would appear to be safe if the holding temperatures were low enough and if the fish were cooked adequately to destroy the toxin. ACA recommended that if it were permitted to irradiate fish the label should clearly state:

> "irradiated fish - store below 2^{o} centigrade and do not eat raw".

5.91 A more detailed discussion on botulism risk is at Appendix 5.

5.92 The Committee notes the concern of many witnesses and recognises the potential dangers of harmful toxins being formed in the absence of normal warning signs of wastage. It also notes that these dangers are similar to those posed in foods processed by conventional methods, such as pasteurisation. It would be essential therefore that food be appropriately labelled.

Aflatoxins

5.93 Mycotoxins produced from certain strains of fungal species growing on some foods, particularly cereals and peanuts, are generally regarded as a public health hazard which should be avoided. This is normally achieved by storing foods under conditions which prevent their moisture content reaching the

critical level needed for fungal growth, a pre-requisite for mycotoxin production. The storage conditions appropriate for different foods to prevent the production of aflatoxin, the most potent mycotoxin, are well known and commercially practised in Australia and many other countries.

5.94 The Committee received several submissions expressing concern that radiation processing of foods could, or would, increase mycotoxin levels and produce mutants with a higher potential to form more potent mycotoxins, especially aflatoxins. The most detailed was from CCFI. The Committee also received detailed comments from ANSTO and a world authority on mould contamination of foods.[17]

5.95 As a general comment CCFI argued that aflatoxins cause malformations in foetuses, cancer and mutations. Some are not only carcinogenic but are amongst the most powerful cancer-causing substances known. ANSTO advised that most of the disorders produced by mycotoxins have been reported only in animals, not humans. Further advice indicated that humans are relatively resistant. In populations where there is a high incidence of hepatitis B virus aflatoxin acts as a co-carcinogen. Aflatoxin is not a real threat in Australia because hepatitis B is rare.[18]

5.96 The CCFI submission reviewed six studies on aflatoxin production. According to the submission the research indicates that irradiation of spores of particular strains of moulds has revealed a stimulatory effect on aflatoxin production with irradiation levels of around 0.5 to 2 kGy, although some research has indicated increased aflatoxin production in some strains at lower dose levels. Some non-toxigenic strains have produced aflatoxins after being irradiated. The submission pointed to other research which produced a mutant through irradiation which is capable of producing toxins from 67 to 138 times more toxic than the non-irradiated parent strain.

5.97 The submission was highly critical of research which suggested that radiation had little impact on aflatoxin production. These experiments were described as "stage managed".

5.98 One such experiment which was designed to approximate normal commercial practice used unsterilised wheat irradiated at 0.2 kGy with a small amount of unirradiated wheat as a control. There were 3 main conclusions:

- unirradiated wheat which was not inoculated with mould showed higher aflatoxin levels throughout the experiment than the irradiated un-inoculated wheat;

- while the rate of aflatoxin formation varied between experimental groups during the experiment after 6 months storage the aflatoxin levels were identical in inoculated wheat whether it had been irradiated or not, and

- humidity and moisture content were the critical factors in the production of aflatoxins.

5.99 The CCFI paper criticised the study on a number of grounds, particularly the very low irradiation dose of 0.2 kGy which the paper argues is a fairly safe level if you do not want "anything to show up".

5.100 Because of the concerns expressed in the submission ACA recommended that the minimum dose for grains should be 6 kGy.

5.101 ANSTO provided a detailed critique of the submission which concluded that most of the research reviewed was performed by irradiating either the fungal spores or the substrate, but not both together as would occur in practice. Substrates were either nutrient liquid media or steam-sterilised foods to which water was

added to provide high moisture levels needed for fungal growth and hence aflatoxin production, a condition not reflecting the normal low humidity storage conditions commercially practised for dried foods to prevent aflatoxin production. Generally aflatoxin levels were measured once only after a set incubation period. Under the experimental conditions used, radiation treatment at doses within the commercially used radiation disinfestation range did not, in general, cause an increase in aflatoxin production.

5.102 Irradiation of deliberately infected wheat at 0.2 kGy stored at 90 per cent relative humidity did not cause an increase in aflatoxin production. ANSTO noted the criticism relating to the use of this dose as being too low for grain disinfestation but pointed out that this is the dose which would be used to disinfest grain and that over the last few years the USSR has used radiation to disinfest more than one million two hundred thousand tons of wheat at a dose of 0.2 to 0.25 kGy. There have been no reports of problems arising because of increased aflatoxin production during storage.

5.103 The Committee sought advice on one study which indicated that 'a mould had mutated to produce 67 to 138 times more toxin. The Committee was advised that it was categorically wrong to infer from these experiments that irradiation increases the ability of the mould to produce aflatoxins. The only conclusions which can be drawn is that the experiment was valueless because of fungal contamination.[19]

5.104 The conclusions reached by ANSTO, JECFI and the FDA were that there was no evidence that the irradiation of foods in their natural state at doses suitable for disinfestation treatments increases the mycotoxin production ability of toxigenic fungal contaminants. Furthermore, other research with artificial systems has shown that if mutants are produced after irradiation they are more likely to be less toxigenic than more toxigenic.

5.105 ANSTO advised that the ACA recommendation for a minimum dose of 6 kGy for irradiation of grains and groundnuts does not appear to have any scientific justification and other witnesses confirmed this.

5.106 On the basis of the detailed reviews received by the inquiry it appears that aflatoxin production in stored dried products, whether irradiated or not, will normally be prevented by controlling the atmospheric conditions to ensure that the critical moisture level necessary for fungal growth is not reached. The Committee is aware of many studies conducted in the laboratory which while they do not approximate normal commercial conditions have indicated a relationship between irradiation and increased aflatoxin formation. It is aware of only one study which was conducted to test the effect under normal commercial conditions. The Committee believes therefore that further investigation is required which replicates normal commercial conditions of handling and storage.

Immune Response

5.107 Some witnesses observed that while the international assessments discuss toxicology in detail there was little discussion of immunology. Witnesses from the Walter and Eliza Hall Institute advised that there was little literature on the effect of food irradiation on immune response systems. The Committee is aware of a Russian study which suggested that some observed adverse effects may be caused by a failure of immune systems and a study conducted by the Indian National Institute of Nutrition (NIN) which specifically examined the immune response in rats fed irradiated wheat.

5.108 Immunologists who appeared before the Committee advised that studies designed to test the immune system would be more complex than simple toxicity or mutagenicity tests. They also advised that it was not clear from first principles why anything in irradiated food should specifically affect those systems (i.e. immune systems) and not affect other systems in the body.

5.109 The Committee sought detailed assessment from two immunologists of the one paper which was designed to test immune response mechanisms in rats given irradiated wheat.

5.110 The study involved feeding rats either freshly irradiated (0.75 kGy) wheat and irradiated wheat stored for 12 weeks. One group of rats was injected repeatedly with several antogens and then bled for assay of serum anti-body levels while in the second experiment the rats were injected with sheep red blood cells and assayed for anti-body producing cells. In both experiments the rats fed freshly irradiated wheat yielded anti-body assay results that were significantly (but not greatly) reduced compared with those fed unirradiated or irradiated and stored wheat.

5.111 One immunologist stated that as a "very preliminary study" each of these experiments would be acceptable but stated that a scientist with any immunological experience would have repeated both experiments several times to establish the reliability of the results before submitting them for publication. He stated the author and the British Journal of Nutrition were immunologically naive in judging it publishable and doubted that any reputable international journal of immunology would have accepted it.

5.112 The Committee was advised that to take such results seriously would require independent confirmation and more extensive and sophisticated testing of the variables.[20]

5.113 A second immunologist advised the Committee that in his opinion the studies are far too incomplete and inadequate to be considered as important evidence in the evaluation of whether irradiated food has the potential for harmful effects upon the immune system. The major criticisms of the study are:

. the small number of animals is simply unacceptable for this kind of complex study;

. the technical nature of the assays used to study anti-body levels is outdated and inadequate, and

. the data is of extremely doubtful significance.

5.114 He was sceptical about the design, reproducibility and interpretation of the paper. He concluded that in the absence of more carefully carried out studies with more reproducible assays on a larger number of animals the paper contributes little to any argument against food irradiation. He added that this does not mean that ingestion of irradiated food was harmless but it simply means this study tells little either way.[21]

5.115 The Committee accepts that the results of the study are not sufficient to reach the conclusion that irradiated grain has an adverse effect on the body's immune system and notes the comment that better designed experiments would need to be undertaken before that conclusion could be reached. As far as the Committee is aware no such studies have been undertaken. These would be necessary before the Committee could reach a conclusion regarding the effect of irradiated grain on human immune response systems.

Genetic Effects

5.116 The opponents of food irradiation who argue that food irradiation may cause genetic damage cite evidence from a series of studies undertaken at the National Institute of Nutrition in India in the 1970's. According to one US cancer researcher, these studies are the "most convincing and comprehensive group of studies to demonstrate the harmful effects of irradiated food". The studies deserve careful consideration since they seem to provide evidence that irradiated food has a biological effect which has been replicated in several animal species, including human children, and the effect appears to be on the genome or peripheral lymphocyte cells, which seems to justify concerns about the delayed genetic effects of consuming irradiated food.[22]

5.117 In these studies, the researchers fed freshly irradiated wheat to a number of different animal species (malnourished human children, macaque monkeys and rats) and measured the occurrence of polyploidy in peripheral lymphocyte cells. Polyploidy is the occurrence of multiples of the normal chromosome complement (46 pairs in humans) in the cells. The authors of these studies assumed that polyploidy was an <u>indirect</u> measure of genetic damage. It needs to be emphasized that this assumption means that data cited on polyploidy do not bear in any way on the capacity of irradiated food to cause DNA damage.

5.118 Researchers at the Indian National Institute of Nutrition undertook studies of fifteen Indian children suffering from severe malnutrition. The children were divided into three groups of five each and received diets containing either unirradiated, freshly irradiated or stored irradiated wheat (0.75 kGy). Children receiving freshly irradiated wheat developed polyploid cells and showed a gradual reversal to nil after withdrawal of irradiated wheat. In contrast none of the children fed unirradiated wheat developed any abnormal cells while children fed stored irradiated wheat ' showed polyploid cells in significantly decreased numbers. The researchers concluded that although the biological significance of polyploidy is not clear its association with malignancy makes it imperative that the wholesomeness of irradiated wheat for human consumption be very carefully assessed. Studies on rats and monkeys conducted by the same Institute confirmed these results.

5.119 Other studies by NIN identified a dominant lethal mutation effect in rats fed freshly irradiated wheat. Dominant lethal mutation is a change in the genetic material of an organism which results in the expression of a dominant characteristic fatal to the organism or its offspring. The researchers concluded that it is necessary to recommend that irradiated wheat be stored for 12 weeks before it can be considered safe for human consumption.

5.120 One study which the Committee's advisers considered well designed also found increased levels of polyploidy cells in the bone marrow of animals fed freshly irradiated wheat but only at dose levels above 20 kGy.

5.121 Four groups of investigators have failed to replicate one or more of the NIN studies on polyploidy. One further group whose work is often cited as a successful replication upon detailed analysis was considered to have failed to demonstrate a link between dominant lethal mutation and irradiated food. For ethical reasons none of the experiments were conducted on humans.

5.122 In one study, scientists from the Indian Atomic Research Centre conducted experiments where wheat was fed to rats within 24 hours of irradiation (0.75 kGy). These studies failed to confirm the NIN results of increased levels of polyploidy.

5.123 The most convincing attempted replication was undertaken on behalf of the International Food Irradiation Project. Two independent scientific laboratories were used. The Committee was advised that the experiments were well designed and protocols were introduced to prevent observer bias. In contrast to the Indian findings neither the incidence of polyploidy nor the incidence of micro-nucleated cells were affected significantly by a diet containing flour prepared from irradiated wheat, irrespective of time of storage. Furthermore the dominant lethal assay revealed no adverse effects on male germ cells of rats.

5.124 The Indian Government established a Committee to assess the conflicting results of NIN and the Atomic Research Centre. The report of that Committee's investigations has not been released but a co-author of the report advised that it found that the NIN experiments were not well designed and consequently their results were found to be imprecise. Also their data raised many questions which cannot at present be explained in the light of well known biological principles and phenomena. He concluded that the NIN data failed to demonstrate any mutagenic potential.

5.125 A past Director of the National Institute of Nutrition and Member of the 1976 Joint Expert Committee (which gave qualified support to food irradiation) has however stated that he had the feeling that all findings which are in favour of wholesomeness of irradiated food are readily accepted without question, while those findings which question this stand are either rejected or viewed with suspicion, either covertly or overtly, as in the case of the Indian studies. He defended the NIN studies and the conclusion that irradiated wheat should be stored for 12 weeks.

5.126 The IFIP sponsored project has been criticised by the London Food Commission on three grounds, namely that:

- it did not test for the effect of freshly irradiated wheat;

- some irradiated wheat had been inadvertently fed to the control group, and

- the experiments were only conducted for 8 weeks.

5.127 The first criticism is incorrect. One of the groups was fed wheat within two weeks of irradiation throughout the course of the experiment. The second criticism may be correct. In the course of this experiment one of the experimental diets was unaccounted for and there is the possibility that it may have been fed to the control animals. The researchers continued the study but added an additional control group to compensate for the effects of this possible error in the allocation of irradiated wheat to the control animals. The final criticism is also incorrect in that the experiments were conducted for 12 and 14 weeks.

5.128 The replicability of the dominant lethal assay of NIN is the most doubtful. Researchers have been unable to replicate the

result of dominant lethal assay despite using larger groups of animals, which have been mated over longer periods, and which in some cases were fed on even more freshly irradiated wheat than that used by the Indian investigators.

5.129 The standing of the polyploidy finding is less clear because well-controlled studies have obtained both positive and negative results. The conflict in findings suggests that, if there is a real effect, it may depend upon some unusual features of experimental design. It should be noted however that the Renner study only achieved increased levels at doses higher than 20 kGy.

5.130 Two substantive criticisms have been made of the NIN studies of polyploidy. The first concerns the adequacy of the NIN investigators' experimental technique; the second concerns the specificity of polyploidy as an index of genetic damage.

5.131 Evidence on the first matter was given by an expert witness in the field of cytogenetics. She argued that the technique used by the investigators to fix the peripheral lympocytes for cytogenetic analysis was likely to produce spuriously high estimates of polyploidy, and had for this reason been abandoned by cytogeneticists. She also argued that the NIN results were contaminated by errors in experimental technique since the rate of polyploidy observed in the group that consumed irradiated food were within the range of subjective error whereas those in the control group were suspiciously low (namely, zero). Other commentators have made the same point.

5.132 The Committee had the opportunity to speak informally with one of the researchers involved in the NIN studies. She defended the design of the experiments and rejected the unrefereed criticisms of her work. She stated that none of the NIN studies published in refereed journals had been withdrawn.

5.133 Another expert witness in the field of cytogenetics was not as dismissive of the NIN studies. He advised that the study of Indian children was difficult to assess because of the small numbers involved and the confounding variable of malnutrition. The technical quality of the metaphase spreads they obtained was not good, but it was more than adequate to identify polyploidy. He concluded however that whilst the findings of this report cannot be dismissed they hardly provide incontrovertible evidence that consumption of freshly irradiated wheat induces significant levels of polyploidy.

5.134 He further stated that in spite of the various conflicting studies there is some evidence to suggest that in humans, monkeys, hamsters and rats an increase in polyploidy (or endoreduplication) in blood lymphocytes does occur after the organisms have been fed freshly irradiated wheat, but not wheat stored for some time after it has been irradiated. This evidence was however far from being absolutely conclusive, particularly as it relates to humans, and further studies would be required to establish this. He could not dismiss the studies on the basis of zero level of polyploids in the NIN control group because it was possible that in the small number of metaphases counted none would have occurred.

5.135 Other witnesses commented that a background incidence of polyploids is not natural and a zero level would be normal. Polyploidy therefore is a result of radiation or a cytotoxin. A US cancer researcher provided the Committee with copies of 4 studies of 20 024 infants which showed zero levels of polyploidy. He argued that these studies indicate that polyploidy did not occur in healthy humans.[23] Both cytogeneticists which appeared before the Committee advised that polyploids would not have been reported in the papers even if they were observed. They could not therefore be used as proof that polyploid cells do not occur in healthy children.[24]

5.136 The second objection to polyploidy is more fundamental, namely, that it is a poor indicator of genetic damage, even when it is measured accurately. One cytogeneticist, for example, argued that polyploidy occurs for a variety of reasons that are unconnected with radiation or other damage (e.g. as a part of the normal process of cell development in the case of megacaryocytes). She argued that a more appropriate measure of genetic damage was the occurrence of an increase in chromosomal breaks and deletions. It is noteworthy that although these structural chromosomal abnormalities were assessed in the NIN studies none of the studies observed any increase in such abnormalities. Nor did any of the attempted replications which also measured breaks and deletions.

5.137 Some critics of the NIN studies have argued that their findings are biologically implausable. The basis of the assertion is that there are a questionable number of connections in the alleged causal chain linking the consumption of irradiated food with genetic damage. Also the alleged progression from polyploid cells to cancer is highly speculative. Indeed it is more likely that polyploid cells will develop from cancer cells than vice versa. The two cytogeneticists who appeared before the Committee confirmed that there was little or no evidence to suggest that cells which are polyploid will subsequently become malignant.

5.138 There is other evidence which is pertinent to the issue of whether the consumption of irradiated food produces genetic effects: the Chinese studies of the effects of feeding human volunteers on irradiated food, and the experience of the Walter and Eliza Hall Institute with mice bred and reared on a wholly and heavily irradiated diet.

5.139 The Chinese investigators conducted a large series of studies on human volunteers in which a wide variety of biological

indicies, including polyploidy, were measured. In none of these studies was any adverse effect of consuming irradiated food observed. The most convincing study was one of volunteers who were fed for 13 to 15 weeks on a diet which consisted of wholly irradiated food. In all of these studies the incidence of polyploidy was measured and in no study did it occur at a higher rate among those who were fed on irradiated food. Unfortunately the results of the Chinese studies have only been reported second hand and have not been subjected to peer review. In addition this summary does not appear to have been written in an objective manner.

5.140 Three witnesses from the Walter and Eliza Hall Institute described the Institute's experience with breeding and raising 61 generations of mice which have been fed exclusively on a diet of irradiated food plus vitamin supplements. The evidence was valuable for the following reasons:

- the researchers had no interest in promoting food irradiation;
- their animals were fed exclusively on food which was more heavily irradiated than the food which is proposed for human consumption;
- because of the high doses and the fact that irradiated food comprises the entire diet of the animals throughout their development, any major genetic effects should be detected, if they occur;
- although a control group of mice was not included, the central focus of research interest at the Institute would allow even small increases in the rates of cancers or birth defects to be detected;

- detailed records have been kept of the fertility of these ice, and of the rates of malformations among animals born in the colony, so that any such effects would also have been detected, and

- sixty one generations of mice have been reared on this diet, (i.e. several million animals), so that a reasonable opportunity has been provided for the detection of any transmissable genetic defects that may be caused by irradiated food.

5.141 The Committee was advised by the Institute that these results were not obtained from formally designed scientific experiments.

Conclusions

5.142 The Committee accepts that the majority of studies undertaken suggest that the ingestion of irradiated food will cause no harmful effects. Notwithstanding this comment there are two areas which are of concern to the Committee. First there are some studies which do indicate that irradiated food may be harmful in some instances. Secondly it notes the comments not only by witnesses opposed to food irradiation but also some regulatory authorities such as the FDA which indicate that many of the earlier studies are inadequate to make a judgement either way concerning the safety of irradiated food. In addition the Committee notes that JECFI in its various reports recommended that further studies be conducted. The Committee also notes the views of its advisers that animal feed trials would be unlikely to show adverse effects because cells of all living animals have evolved mechanisms designed to protect against the radiolytic products formed in irradiated food.

5.143 Accordingly the Committee recommends that:

the Australian Government request the World Health Organization to:

- **review existing data relating to the safety of irradiated food;**
- **produce a fully referenced report on the safety of food irradiation, and**
- **identify those areas where further research is required.**

Endnotes

1 New Zealand Institute of Nuclear Sciences.
2 Louria, D., Submission to the Committee.
3 United States Food and Drug Administration, Correspondence with the Department of Foreign Affairs and Trade.
4 Ames, B., "Dietary Carcinogens and Anticarcinogens", Science, Vol. 221.
5 Louria, D., Submission.
6 Julius, H., Submissions to the Committee.
7 Julius, H., Submissions.
8 Louria, D., Submission.
9 United States Food and Drug Administration, Correspondence.
10 Robotham, F.P., Advisers Report to the Committee.
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12 Tritsch, G., Submission to the Committee.
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17 Pitt, J., Submission to the Committee.
18 Pitt, J., Submission.
19 Pitt, J., Submission.
20 Harris, A., Submission to the Committee.
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23 Tritsch, G., Submission.
24 Moore, R., Submission to the Committee.

6. NUTRITION

Introduction

6.1 Any consideration of food irradiation must take account of the impact of the technology on the nutritional status of the population. As previous Joint Expert Committees on Food Irradiation observed many essential nutrients in foods, particularly vitamins, are destroyed to some extent by irradiation. The magnitude of such losses will depend on many factors including radiation dose, environment during irradiation and post irradiation conditions. It is therefore important to:

- examine the changes which occur in the nutrient content of foods following irradiation;

- determine whether the bio availability of nutrients is in any way altered, and

- establish whether changes, if they do occur, would have possible adverse nutritional consequences.

6.2 The 1976 JECFI observed that relatively small changes in nutrient composition or bio availability in foods that are consumed in considerable amounts in habitual diets may acquire nutritional significance, whereas similar changes in foods that are eaten only in small quantities would be less likely to affect nutritional balance. Thus alterations in the nutritional qualities of meat and fish where these foods constitute a major part of the diet would be more serious than changes in foods like papaya, mushrooms and strawberries. In several developing countries large population groups obtain a very high proportion of several nutrients from a single source.

Effect on Nutrients

6.3 There were various views presented to the Committee concerning the impact of irradiation on nutrients. The FDA

concluded that the available literature indicated that there are no nutritional differences between unirradiated food and food irradiated at levels below 1 kGy. Other scientific panels of review have concluded that the available scientific evidence indicates that food exposed to ionising energy, under the conditions proposed for commercial application, possesses a nutritional adequacy which compares favourably with that of fresh foods or with that of foods processed by well established conventional methods.

6.4 Many witnesses who are opposed to food irradiation are not satisfied with the conclusions of these reviews. The College of Dietitian-Nutritionists in Private Practice, for instance, provided the following table on vitamin loss in irradiated food to the Committee.

TABLE 5
VITAMIN LOSS IN IRRADIATED FOOD

Vitamin A	milk and cheese	60 - 78%
	meat	43 - 76%
	chicken	53 - 95%
	shrimp	2 - 27%
Vitamin B1	milk	35 - 85%
	grains	20 - 86%
	beef, chicken	42 - 96%
	fish	15 - 90%
Vitamin E	milk	40 - 60%
	grains	7 - 45%
	eggs	17%
	nuts	19 - 32%
Vitamin C	potatoes	28 - 56%
	fruits	20 - 70%
Vitamin B2	milk	24 - 74%
	beans	48%
	meat	8 - 38%
Vitamin B6	milk	15 - 21%
	beans	48%
	meat products	10 - 45%
	fish	26%

Source: College of Dietitian-Nutritionists in Private Practice

6.5 The College advised that many proponents of food irradiation say that the losses are equivalent to losses in normal cooking or storage. It was claimed this was misleading because food that has been irradiated continues to lose its vitamin activity during prolonged storage. Losses would be greater in irradiated foods than for normal storage conditions. Cooking irradiated food results in greater vitamin loss than in normal processed foods. Generally vitamin C and some of the B group vitamins together with vitamin E are the most radiation sensitive vitamins.

6.6 There are undoubted changes to the nutrient content of irradiated food. Amino acids in solution are sensitive to irradiation doses but are less so when irradiated in a whole food. Some amino acids show greater losses than others (e.g. cystine/cysteine). In addition chemical changes occur at some doses which may lead to alterations in the normal properties of foods. The effects of ionising energy on fats are similar to changes resulting from heat or oxiciditive processes. Some gross changes can occur, for instance, flavour changes in meat. One witness was particularly concerned about changes in polyunsaturated fats which could have important nutritional consequences.

6.7 While the mineral content of food does not change due to irradiation, associated changes in other food components can affect their bio availability.

6.8 In a submission to the Committee, ANSTO advised that all food processing treatments (canning, drying, freezing, cooking) may result in a partial loss of vitamins. ANSTO points out that processed potato flakes, toasting of bread and even pasteurisation of milk, which is essential to provide a safe food, result in a loss of vitamins. Normal post harvest storage of some fruits will result in certain vitamin losses.

6.9 ANSTO also advised that it is misleading to show vitamin losses without referring to the dose, whether or not the vitamin was irradiated in a solution or in a food, whether or not the food is a likely candidate for irradiation or if the food has been irradiated, handled and stored in a manner which relates to proper commercial practice.

6.10 While many witnesses pointed to the loss of vitamin C when potatoes are irradiated at low doses ANSTO's research, which was confirmed by other studies, indicates that six months after harvest irradiated potatoes stored at 20°C had retained 98 to 109 per cent of their original level of reduced ascorbic acid content. The research further indicated that there were no significant differences between the levels of total ascorbic acid in unirradiated and irradiated potatoes - variety had more influence than irradiation on the ascorbic acid content of potatoes.

6.11 ANSTO pointed to other research which indicates no loss in vitamins in particular products. Radiation induced losses of any B vitamins are usually less than 10 per cent at commercial doses ' except for thiamin and pyridoxin which can be protected by vacuum packaging and/or freezing the food. Thiamin content of potatoes is not affected by irradiation.

6.12 The Committee notes that some nutrients are reduced and others are changed but believes that the significance of these effects can only be determined if an examination is made of the sources of these nutrients in the diet and the significance of these nutrients in foods which will be irradiated.

6.13 A number of witnesses expressed concern about the effects of combining irradiation with other processes, including cooking. In addition various scientific panels of review observed that more information would be desirable. The material available to the Committee does not indicate clearly whether effects would be

additive or synergistic or that there would be any effect at all. Some studies have indicated that losses with combination treatments on fruits and fish were no higher than would be expected from the separate treatments. Some other studies indicated that some nutrients were unaffected by irradiation or cooking when applied separately but indicated losses when the two processes were combined.

6.14 One researcher observed that explanations for the "occasionally" observed synergism between radiation and heat are speculative at this stage.

6.15 The Australian Government Analytical Laboratories advised the Committee that there would be value in a study designed to examine a number of vitamins in foods and to determine the degree of change as a result of irradiation and/or cooking. The Committee has been informally advised that the Government has provided funds to enable such an examination to be undertaken. Previous JECFI's have also recommended that further research be undertaken in this area.

Significance of Changes

6.16 The CSIRO Division of Human Nutrition advised that irradiation would not have an adverse impact on human nutrition in Australia because the doses employed would be low and by far the bulk of available food would not be irradiated. By way of example the Division referred to vitamin E (which can be virtually destroyed by irradiation in some foods). The major sources of vitamin E are margarine and butter, fats and oils. None of these foods is suitable for irradiation.

6.17 As discussed in a previous Chapter some evidence suggests that only a small range of foods (if any) will be irradiated in Australia and of the food groups which may be candidates only a small quantity of those would be irradiated. It is the Committee's

assessment that, in the short term, some tropical fruits, tomatoes and strawberries are the only possible candidates for irradiation. However, other produce which has been suggested includes poultry and fish fillets. The Committee sought the assistance of the Commonwealth Department of Community Services and Health and ANSTO to determine the impact of irradiation on nutrition if the technology was applied to these groups of food.

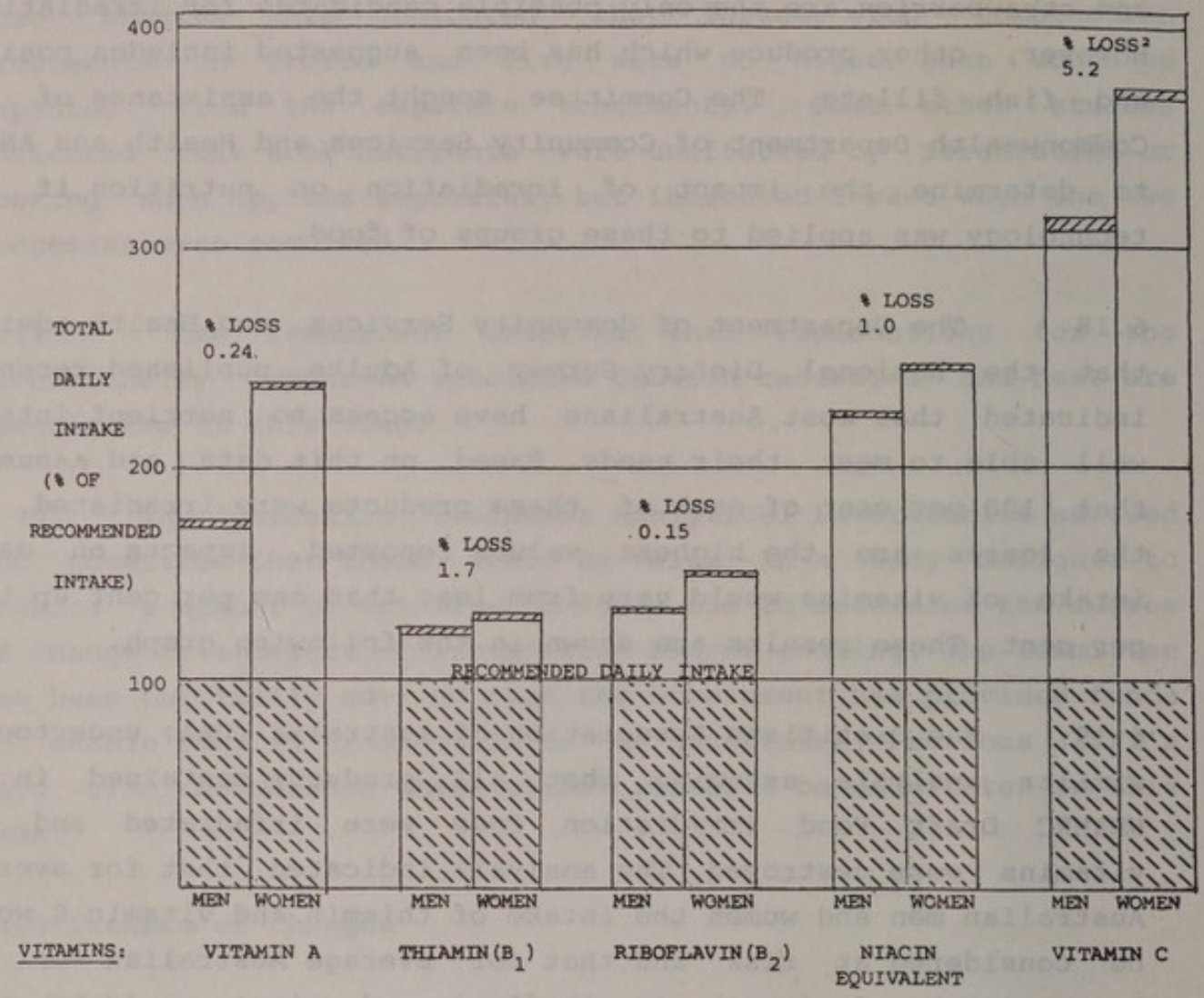
6.18 The Department of Community Services and Health advised that the National Dietary Survey of Adults published recently indicated that most Australians have access to nutrient intakes well able to meet their needs. Based on this data and assuming that 100 per cent of each of these products were irradiated, and the losses are the highest values reported, impacts on daily intake of vitamins would vary from less than one per cent up to 5 per cent. These results are shown in the following graph.

6.19 The Dietitians Association of Australia (DAA) undertook a similar analysis assuming that all products contained in the NH&MRC Draft Food Irradiation Code were irradiated and all vitamins were destroyed. The analysis indicated that for average Australian men and women the intake of thiamin and vitamin C would be considered at risk and that for average Australian men and women intake of vitamin A, riboflavin and niacin would be more than adequate.

6.20 It is unlikely that every food identified as a possible candidate, nor all foods allowed for in the NH&MRC Code, would be irradiated. In addition each example overestimates the probable vitamin destruction.

6.21 On the basis of information provided by the Nutrition Section of the Department of Community Services and Health and the Dietitians Association of Australia it could be concluded that the impact of irradiation on the nutritional value of foods for the average Australian would be insignificant. The Committee however has difficulty with the concept of the "average" Australian as this may not take sufficient account of individual diets.

EFFECT OF COMMERCIAL RADIATION TREATMENT OF 100% OF SELECTED FOODS[1] ON DAILY INTAKE OF CERTAIN VITAMINS BY AUSTRALIAN CONSUMERS



▨ = Estimate of percentage of vitamin intake lost through irradiation. (The hatched area is not to scale, but overstated to register the small amounts involved, even using the worst case (highest losss reported) for the estimations.

1. Tropical and berry fruits, tomatoes, potatoes, poultry, fish.

2. Maximum value because losses have generally been reported as loss of reduced ascorbic acid only, rather than as loss of total ascorbic acid, which would be much less.

Source: Australian Nuclear Science and Technology Organisation based on data provided by the Department of Community Services and Health

"At Risk" Groups

6.22 There are some sub-groups of the Australian population who are more nutritionally at risk than others. These groups could include the elderly, people on low incomes, some aboriginals, some vegetarians and alcoholics. The ACA inquiry concluded that the concept of "insignificant vitamin loss" is only relevant when taken in the context of "adequate vitamin intake". In addition there are people who while they consider that they consume a balanced diet do not realise that they may be consuming foods deficient in some nutrients.

6.23 A medical practitioner specialising in nutrition advised the Committee that the use of recommended daily allowances of particular nutrients is misleading, as recommended daily allowances apply to populations and not to individuals. She advised that because of defective enzymes in some persons extra vitamins are needed to facilitate proper functioning. Even in a normal healthy person there is a chance of needing more than the RDA of one of the more than 40 essential nutrients. Other medical practitioners with specialist nutritional qualifications agreed with these views.

6.24 The witness concluded that even a marginal reduction in the vitamin content of food due to irradiation and longer storage was likely to have an adverse effect on the health of Australians. Unless there are assurances that irradiation will not increase the prevalence of ill health and degenerative disease the process should be prohibited.

6.25 The College of Dietitians-Nutritionists in Private Practice strongly disagreed with statements which stated that nutritional losses caused by irradiation are not significant to Australians who enjoy an abundance of food at all times. Referring to the report of the Better Health Commission the College suggests

that in the case of vitamin C the average figure greatly overestimates the actual intake. In fact, intakes generally would border on the recommended levels. If food irradiation were added to the losses caused by cooking and storage the College concluded that Australians will not have adequate sources of vitamin C. The same was true for other nutrients.

6.26 One witness was sceptical about the conclusions relating to the impact of irradiation on the nutrient intake of individuals. He believed that it was not possible to take a total diet study because it does not take account of individual differences. He referred to an examination of 15 000 healthy Australians which showed over 30 per cent to be deficient in at least one vitamin.

6.27 The Department of Community Services and Health commented that the College had drawn incorrect conclusions from the data referred to in the Better Health Commission report. The Better Health Commission used apparent consumption figures. In contrast however data based on actual diet surveys indicates that on average, Australian men and women are able to obtain approximately three times the recommended intake of vitamin C. The Department commented that these vitamin C intakes refer to the content of the diets as consumed and have therefore taken into account usual losses before consumption. The recommended daily intakes also include a large margin of safety.

6.28 Concern was also expressed about those who suffer from allergies or other adverse reactions to food. The Hyperactivity Association of South Australia and the Allergy Association of Australia (Tasmania) commented that it is already difficult to find healthy, nutritious, unprocessed food. Those affected would have to attempt to avoid all irradiated foods due to the real and potential effect on health. The Allergy Association commented that the reduction of the vitamin content of food would retard the recovery and increase the susceptibility of the population at large to allergies.

6.29 The Department of Community Services and Health advised that at risk groups will not be protected necessarily by the banning of new technologies. In the case of those with nutrient deficiencies identification of the factors contributing to the risk and education, as well as perhaps other social interventions, are needed to assist these people in the selection of an adequate diet. The Department stated that education was the key to removing the obstacles to appropriate choice once other social barriers have been removed.

6.30 The Dietitians Association of Australia stated that the problem with many individuals who are at nutritional risk was not so much that the vitamins have been lost from the food they consume but rather they consume foods which are not good sources of nutrients, particularly vitamins. DAA commented that if food irradiation allowed improved transportation of foods around Australia and overseas the nutrient intake of the Australian and other populations could be increased as a greater variety (choice) of nutrient sources became available.

6.31 The Department of Community Services and Health advised that people who may have allergies or other adverse reactions to food or a component of food needed special kinds of help. They would need a proper medical and diagnostic evaluation to identify the substance(s) in the diet to which they were reacting, they needed information to help them avoid the substances to which they were adversly reacting and they needed assistance in planning their diets so that nutritional safety was not jeopardised. Education, including information provided as labelling, was the primary way to help affected individuals.[1]

6.32 A Professor of Medicine with expertise in nutrition stated if education programs were effective those on marginal diets would be adequately catered for. However he observed that those groups most vulnerable are often those who are least able to make changes.

Food Intake Surveys

6.33 The Burgen Report commented that it is standard practice for food manufacturers to obtain nutritional data when making a new application of an accepted process and for government to review the consequences of changes in food technology. Burgen concluded that it would be equally appropriate if the process were permitted in the United Kingdom for the pattern and extent of use of food irradiation and the nutritional consequences to be kept under review. ACA recommended that Federal, State and Territory Departments of Health keep up to date records of quantities of specific food items which are being irradiated.

6.34 A nutritionist believed that regular food intake surveys should be conducted. Data should be collected to enable conclusions to be drawn in respect of gender, age and socio economic characteristics. It was only with the collection of this type of data that one would be able to evaluate the level of risks which are high for particular individuals and sections of the community.

Conclusions

6.35 The Committee agrees that if food irradiation is restricted to a limited number of food types and only a small quantity of those foods are irradiated, as was suggested by some evidence, it is likely to have little impact on the nutritional status of most Australians. The Committee notes however that if food irradiation were to include all the types of foods recommended by the Codex Alimentarius Commission there is insufficient firm data on the practical effects of consuming irradiated food to conclude that the nutritional status of the Australian population would not be reduced. This is particularly the case for those "at risk" groups of Australians whose diets might be nutritionally inadequate as stated by some expert witnesses.

6.36 The Committee notes that the Australian Government Analytical Laboratories and various JECFI's have identified areas where data is lacking and further investigation is warranted. Accordingly the Committee recommends that:

- **the Australian Government request the World Health Organization to review all existing data relating to the impact of food irradiation on nutrients to identify areas where data is adequate and areas where more research is required, and**

- **produce a fully referenced report on the impact of food irradiation on nutrients, with particular reference to the impact on human health.**

6.37 The Committee notes on the basis of evidence given that irradiated food might never form a significant proportion of the diet of the Australian population, or even individuals. The Committee agrees with various panels of review, including the ACA, that if food irradiation were to be approved the quantities and types of irradiated food should be monitored. In addition, the Committee believes that the consumption patterns of irradiated food be monitored in a manner which would enable public health authorities to identify at risk groups who may consume a significant quantity of irradiated food.

6.38 Accordingly the Committee recommends that:

if the irradiation of food were to be approved the Minister for Community Services and Health request Commonwealth and State Public Health Authorities to monitor the quantities and types of foods which are irradiated.

6.39 The Committee further recommends that:

if the irradiation of food were to be approved the Minister for Community Services and Health ensure that all future dietary intake surveys are designed in a manner which would enable identification of those at risk groups who may consume irradiated food as a significant proportion of their diet and whose diet may be nutritionally inadequate.

Endnote

1 Department of Community Services and Health, Supplementary Submission to the Committee.

7. RADIOLOGICAL AND ENVIRONMENTAL SAFETY

Radiation Dose Limits

7.1 The International Commission on Radiological Protection (ICRP) recommends a system of dose limitation, the main features of which are:

- no practice shall be adopted unless its introduction produces a net benefit;

- all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account (known as the ALARA principle), and

- the dose limit to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission.

7.2 These recommendations are adopted for Australia by the National Health and Medical Research Council and are published as "Recommended Radiation Protection Standards for Individuals Exposed to Ionising Radiation". The dose limits currently recommended by NH&MRC are:

- whole body dose limit for radiation workers - 50 millisievert (mSv) (5 rem) per year.

- whole body dose limit for a member of the public - 1 millisievert per year (averaged over a lifetime, not more than 5 mSv to be received in any one year).

7.3 Each State and Territory has regulations relating to radiation exposure. They all incorporate the recommendations of NH&MRC.

7.4 The Committee was advised that ICRP is currently reviewing its current dose limits, which effectively date from 1977. Recent analysis of exposure data from Hiroshima and Nagasaki has suggested that existing risk estimates may be about two times too low. ICRP has considered the fresh data but does not intend to publish new recommendations before the due date of 1990. The UK National Radiological Protection Board has however published interim recommendations suggesting dose limits of 15 mSv per year for radiation workers and 0.5 mSv for members of the public (for any one radiation site).

7.5 The Committee was advised that if such dose limits were adopted within Australia it would not affect the operation of irradiation facilities as existing doses, for both workers at the plants and the public living nearby, are well below those limits.[1] The advisers report on radiation safety is at Appendix 6.

7.6 Most decisions about human activities are based on an implicit form of the balancing of costs and benefits leading to the conclusion that the conduct of a chosen practice is "worthwhile". Less generally, it is also recognised that the conduct of the chosen practice should be adjusted to maximise the benefit to the individual or to society. In radiation protection it is becoming possible to formalise these broad decision-making procedures, though not always to quantify them.

7.7 A number of groups pointed to the potential dangers to human health, both to workers in irradiation plants and the general community, of exposure to radiation. Years after exposure people may suffer from cancer or their children may be born with genetic damage. Even below the level where immediate effects are experienced there remains an increased risk of cancer.

7.8 Opponents of the use of nuclear technology argued that there is no dose below which effects do not occur. Proponents of

nuclear technology point to the fact that humans have evolved and continue to live in a sea of background radiation. There is no conclusive evidence that radiation doses at, or slightly above, the background radiation level are harmful.

7.9 Both groups agreed however that, in assessing the potential effects of any radiation exposure, it should be assumed that the risk is proportional to the dose (i.e. the higher the dose the greater the possibility of some effect). The opponents of nuclear technology argued that the extremely large doses required for the irradiation process could result in exposure of workers in the industry. A Committee of the European Parliament concluded that workers in the industry are exposed to unnecessary risks.

7.10 A number of witnesses referred to the fact that over the years allowable maximum exposure rates have been reviewed and reduced. At any given time the known effects will always be equal to, or less than, the real effects. It was claimed that a worker receiving the allowable dose each year would run a risk 8 to 16 times higher than is recognised for a "safe" industry. A "safe" industry recognises that 1 worker in 10 000 will die each year or over a lifetime 1 in 200 workers will die from an accident at work.

7.11 ANSTO advised that the ICRP maximum permissible dose does not represent a level of radiation to which workers are routinely exposed but a level that must never be exceeded. In general, worker levels of exposure are considerably below this maximum whole body dose limit. Worker levels of exposure are determined in accordance with the ALARA principle. ANSTO concludes that it may therefore be seen that the suggestion in the evidence that over a lifetime a number of workers will die because the setting of the 50 millisievert minimum safe standard was inappropriately high is unjustifiable.

Radiation Levels at Australian Plants

7.12 In 1986 the Victorian Government appointed a Radiation Safety Review Panel to examine the operations of the Ansell Steritech Plant in Dandenong. In addition the Committee requested its adviser on radiation safety to conduct a review of the Ansell Steritech and Johnson & Johnson plants in New South Wales. Doses recorded by workers at each of the plants were generally zero. The highest dose recorded at the Dandenong plant, for instance, was 0.8 per cent of the current maximum dose limit as measured by personal film badges. This dose was received during source loading operations, not during routine operations. The monitored radiation levels around the plants are, with the exception of some known positions, at about background levels. The positions of slightly higher than background radiation levels are such that workers would not be in those positions for any length of time.

7.13 The very low recorded exposure indicates clearly that, under normal operations, working at the gamma irradiation facilities does not constitute a significant radiation hazard to employees. The radiation levels at the periphery of the plants during normal operation are indistinguishable from background levels, whether the source is in the exposed position or in the pool.

7.14 Given that workers are exposed to levels of radiation close to zero, concerns were expressed about the levels at which State health authorities would query exposure levels. Some authorities would investigate safety procedures and conditions if film badges indicated that a person had been exposed to a quarter of the annual allowable dose. At this level cancer rates could increase by nearly 20 per cent,[2] assuming a linear dose/effect relationship.

7.15 The Committee was advised that these figures are misleading. They imply that the worker would be exposed to these levels (i.e. 25 per cent of maximum allowable annual dose) over a working lifetime. This would be unlikely. A State regulatory authority stated that if levels such as this were observed a complete re-evaluation of the procedures would be required so as to determine causes and action required to change those procedures. No doses at Australian irradiation plants have exceeded 0.8 per cent of the annual dose limit. Exposure at these levels would result in an increased risk of 0.012 per cent.[3]

7.16 Gamma irradiation facilities have operated within Australian since the 1960's. In that time, while there have been breakdowns and stoppages at the plants, there have been no accidents which have resulted in a radiological hazard to workers or members of the public. The Federated Storemen and Packers' Union of Australia, the union which represents workers in the gamma irradiation plants, stated that the Union has no record or knowledge of any workers compensation claim lodged by any of its members in relation to irradiation processes.

7.17 The Committee was told that the International Chemical and Energy Federation, supported by the major unions in Britain, Canada, Australia and the United States, has called for an immediate five-fold reduction in exposure limits with a target of a ten-fold reduction to be phased in. Australian irradiation plants could easily operate within these limits.

7.18 The Committee concludes that in normal operation irradiation plants operated in the manner of Johnson & Johnson and Ansell Steritech will not present a radiation hazard to either plant personnel or nearby residents.

7.19 Approximately two-thirds of radiation workers in Australia are monitored by their employers through the monitoring

service provided by the Australian Radiation Laboratory. Since the beginning of 1987 an accumulative total of exposure has been kept for the workers registered with the Laboratory. This will enable a lifetime exposure from 1987 onwards to be known and maintained. There is no mechanism to monitor workers who leave the industry.

7.20 A radiation protection officer agreed that there would be value in maintaining health and radiation records of workers in the industry. Coupled with the radiation dose records currently compiled by the Australian Radiation Laboratory such data would enable future investigators to carry out detailed epidemiological studies.

7.21 Accordingly the Committee recommends that:

the Minister for Community Services and Health investigate ways in which the health of radiation workers can be monitored both during their period as workers in the radiation industry and after they leave the industry.

Staff Training

7.22 Safety not only depends on the good design of the facility but also on the adequate training of the operators. Safety requires the establishment of adequate working procedures, their approval by radiation control authorities and strict adherence to them by operators who must be well trained in the possible hazards of their work and the means of avoiding or minimising them by strict compliance with the established procedures.

7.23 It was claimed that in all serious accidents in the nuclear power industry human error has been responsible for, or has contributed significantly to, the resulting hazard. There is a

world of difference between highly skilled scientists handling radioactive materials under laboratory conditions and blue collar workers in an industrial setting where the emphasis is on cost cutting and profit maximisation. A witness concluded that it would be foolish to imagine that the human error/laziness/incompetence element will be removed from profit oriented industry, including the food irradiation industry. The Committee notes that there are examples from overseas operations to confirm this view.

7.24 The Committee notes the need for effective legislative controls to ensure, inter alia, that adequate staff training is carried out, that errors are eliminated and that incompetent and lazy staff are not licensed to operate or work in irradiation plants.

7.25 The plant managers at the three gamma irradiation facilities have all attended appropriate courses. All plant operators have Atomic Energy of Canada Limited (AECL) competency certificates. The Committee was advised however that there is room for improvement in safety training. While each of the plants have a radiation protection officer available at call the training of operators relates to plant operation and the automatic running of the plant. This training takes place when new sources are installed. The course contains little or no radiation safety information. Ad hoc radiation safety lectures are given to operators but it was not possible to assess the relevance or adequacy of this training.[4]

7.26 The Committee recommends that:

the Minister for Community Services and Health request State Ministers to require that plant supervisory staff have radiation safety training at a level appropriate to their degree of supervision to include:

. some understanding of radiation physics;

- biological effects of radiation;
- radiation units;
- control and emergency procedures, and
- plant safety design.

7.27 The Committee further recommends that:

the Minister for Community Services and Health request State Ministers to require plant operators be given radiation safety training to include:

- the effects of radiation;
- operation and use of radiation monitors;
- exposure limits, and
- plant safety and emergency procedures.

7.28 The Committee considers that a refresher course should be held every two years.

7.29 The Committee noted that a radiation protection officer was not located on site during plant operations. The Australian Radiation Protection Society believe that while it is essential for a radiation protection officer to be available to each company the need for a person to be employed directly by the company depends on the size of the facility. The Society advised that not every facility needs a full-time radiation protection officer on the site for the whole time and it was not considered necessary for the three commercial gamma irradiation facilities. The Committee accepts this advice provided that on site personnel are trained in the manner recommended in previous paragraphs.

Plant Design

7.30 The previous paragraphs discussed the risks to workers and the community in general of the operation of irradiation facilities in normal operation. The Committee also examined the

safety mechanisms and procedures which operate in the plant to ensure that accidental exposure to radiation is minimised.

7.31 The Ansell Steritech and Johnson & Johnson facilities which were designed and constructed by Atomic Energy of Canada Limited incorporate safety procedures to prevent accidental exposure to the cobalt 60 source.

7.32 Products are sterilised by irradiation within a concrete irradiation chamber consisting of concrete walls nearly 2 metres thick. When not in use the radioactive source is stored in a deep water storage pool which is located directly below the concrete chamber within which the products are irradiated. In this position the water acts as a shield against the gamma rays emitted from the source and enables immediate access into the irradiation chamber. A hoisting mechanism enables the source to be raised into the chamber or lowered into the pool as required. Product cartons requiring processing are loaded into carriers in a pre-irradiation storage area. An automatic conveyor system then transfers the product carriers into the irradiation chamber. A source pass mechanism indexes the product carriers around the source and the conveyor system transfers the carriers to the sterile post irradiation storage areas for unloading.

7.33 There are a number of design and safety features to ensure proper protection of plant operators and the general public. The plants depend for their operation on electric power. Any disturbance to the power lasting longer than five seconds will automatically result in the source lowering into the pool under gravity. Other facilities close down which requires full start-up action, involving a number of safety procedures, to restore operation.

7.34 The fundamental fail-safe principle of the plant is that the source will sink into the storage pool under its own weight. In the event of the source rack being stuck in the up position

other safety devices would preclude access to the irradiation chamber by personnel. There are various other safety mechanisms which are described in Ansell Steritech's submission.[5]

7.35 The Radiation Safety Review Panel established by the Victorian Government considered five areas of concern, namely structural reliability, electrical reliability, radiation safety including training, emergency preparedness and safety of the transportation of radiation sources to and from the plant. A number of recommendations were made to ensure that the high safety standards are maintained. The Panel was of the view that no major changes were needed to the present operation of the plant.

7.36 The Review Panel concluded that with minor exceptions the Dandenong plant of Ansell Steritech operates in a safe and satisfactory condition, complies with Victorian radiation safety regulations and does not present a significant radiological hazard to either plant operators or members of the public. Similar conclusions were reached following inspections of the plants operating in New South Wales.[6]

7.37 The Committee was provided with detailed criticisms of the Sydney Ansell Steritech plant prepared by an engineer and a member of the Friends of the Earth. Criticisms included no power back-up and reliance of the force of gravity to return the source to the shielding pool, difficult access through small holes and no remote controlled system or equipment to cope with an unshielded source, ineffectual safety arrangements for personnel and no system to remove bacteria and viruses from air discharged.

7.38 Both Ansell Steritech and the Chairman of the Victorian Government Review Panel responded to these criticisms. Both witnesses clearly indicated that the reliance on gravity to return the cobalt 60 source to the shielding pool is more reliable than any power source developed for this purpose. In addition should the cobalt 60 source remain unshielded it would present no

radiological hazard. Other criticisms indicated a lack of understanding of the safety features. Detailed responses are shown at Appendix 7.

Accidents

7.39 A number of witnesses pointed to accidents which have occurred in overseas plants. One witness stated that in many cases the management of those plants chose to cover up the accidents and deliberately polluted the environment with radioactive waste rather than take proper courses of action. In a number of incidents personnel were exposed to radiation and some died.[7] No such incidents have occurred at Australian plants.

7.40 The US Company responsible for several of the incidents has had its operating licence revoked and the company has terminated its relationship with its founder and president.[8]

7.41 A death occurred in a Norwegian experimental irradiation facility when an installed gamma monitor was not replaced during servicing. This co-incided with the failure of a "source up" warning light, and the technician who investigated entered the irradiation cell without a hand-held monitor. In Australian plants the entrance maze monitors are duplicated and a hand-held radiation monitor is firmly fixed to the access door key.[9]

7.42 Ansell Steritech was criticised for failing to include advice of accidents, both at Ansell Steritech's Dandenong plant and Johnson & Johnson's plant in New South Wales, in a list of incidents at gamma irradiation facilities. The Committee was advised that this was not an attempt to withhold information relating to the safety of Australian plants but rather reflected the fact that the Australian incidents involved no radiological hazards.

7.43 The Ansell Steritech incident related to a source jam at its Victorian plant in 1980. A product basket gate jammed in overhead rollers, buckling the gate and jamming the source rack. The plant had shut down but the source did not return to the bottom of the pool. The Plant Manager advised the Committee that:

> "eventually we cut the cable and it just went straight down to the bottom of the pool".[10]

7.44 It appears that this is not strictly correct. In fact the cable snapped as a result of cable manipulation in an effort to free the source. The cable disappeared into the irradiation chamber and it was not for 12 hours that it was realised that this had freed the source and it had descended into the pool.[11]

7.45 The Committee has been advised that at no stage was there any radiological hazard to personnel either in the plant or to members of the public. This would have remained the case irrespective of how long the shut-down had occurred. The source was stuck in an up position for five and a half hours. Modifications made to the plant should prevent a similar incident.

7.46 Briefly, a fire at the Johnson & Johnson plant in 1982 was caused by a cardboard product box lid opening and jamming the product line. A relay failed which should have caused the source to descend to the bottom of the pool when the line stopped. The source was up for 14 hours irradiating stationary cardboard boxes, one of which eventually caught fire. The fire activated a thermal detector and the sprinkler system came on automatically. This, in turn, resulted in a plant shut-down and the source descended into the pool. The incident had not been detected earlier because the plant was operating automatically. Changes in both plant operations and maintenance procedures have been instituted to prevent a reoccurrence. The Committee has been advised that the fire did not present a radiation hazard to any personnel at any

stage. The personnel from the plant and State regulatory authorities involved carried out their procedures in a correct manner.

7.47 The technical expertise available within Australia to respond to accidents such as these was raised by a number of witnesses. In the event of an emergency AECL technicians can be called from Canada. The Committee was requested to recommend the proper training of technicians in Australia capable of handling any type of accident in a gamma irradiation plant. It seems that this concern in part results from these two incidents and what appears to be the inability of plant operators and regulatory authorities to deal with the emergencies.

7.48 However, in neither case were AECL technicians involved in the emergency response procedures. The Johnson & Johnson fire was handled entirely by plant staff and New South Wales authorities. An AECL technician visited the plant two days after the fire to assess the cause. In the case of the Ansell Steritech incident because the cable snapped the source sank to the bottom of the pool. Canadian technicians were not required other than to assess the damage and assist in reassembly. If the cable had not snapped the source would have been freed by remote manipulation which would have required the assistance of Canadian engineers.

7.49 No witness with experience in radiation protection considered it essential that personnel with the experience and equipment of AECL technicians be located permanently in Australia at any of the plants or at ANSTO. The Committee was advised that it was irrelevant whether people could respond within an hour or whether the response time was a number of days provided that the source was contained within the irradiation chamber.

7.50 It was suggested that there may be grounds other than safety for the establishment of an Australian emergency response team. A number of witnesses observed that the technical expertise

to deal with major accidents already exists in Australia. Some specialised equipment would need to be acquired and special training may be required to familiarise staff with particular design features of the AECL plants. The establishment of such a team would increase public confidence and would enable Australians to provide emergency assistance to neighbouring countries with irradiation facilities.

7.51 Accordingly the Committee recommends that:

the Minister for Industry, Technology and Commerce request the Australian Nuclear Science and Technology Organisation to develop suitably equipped radiation safety specialists and engineers to provide assistance in the event of any unusual occurrences at Australian and regional irradiation facilities.

Maximum Credible Accident

7.52 The Managing Director of Ansell Steritech considered that the maximum credible accident which could occur would be for a person to enter the irradiation chamber with the source rack in the up position. The Victorian Panel of Review on the other hand considered that the maximum credible accident would be for a pencil to exit the chamber.

7.53 Ansell Steritech considered that the only way a person could enter the chamber was to wilfully bypass the many safety interlocks. A pencil exiting the irradiation chamber was not considered to be a credible accident.

7.54 If a pencil becomes dislodged and falls into the pool or stays within the cell it does not present a major hazard as the plant can be shut down and assistance sought from AECL. Such an event would not represent a major hazard to either plant personnel or members of the public. The possibility of a pencil or part

thereof being dislodged from the source frame and being carried outside the shielded area on a product box or the conveyor system was considered in some detail by the Victorian Review Panel because of the extremely dangerous situation which would arise from such an eventuality. Essentially, there are three safety features which militate against this:

- The source pencils are held in a rack of six modules. Each pencil is slotted into a channel at the top and bottom of the module and slid into position. When full (42 pencils), a hinged end of the module is closed, thus holding the pencils firmly in the module. These modules in turn are held in the rack by sliding them into vertical channels at each end of the modules.

- A shroud is fitted to the conveyor structure as such that, should a pencil be dislodged from the frame, the shroud provides a physical barrier between the source frame and the product boxes. The design of the shroud is such that a dislodged pencil would fall to the bottom of the pool.

- A gamma radiation monitor is installed in the product exit maze. This monitor sounds an alarm if the radiation level in the maze exceeds a preset level. Operation of the alarm will shut down the plant, preventing further movement out of the maze by the errant pencil.

7.55 In the Panel's view these three safety features ensure that a pencil or part thereof cannot be transported out of the cell on a product box or the conveyor. Nevertheless, the Panel concluded, if such an accident should happen, the plant would need to be evacuated and the Radiation Safety Section, Police and emergency services notified. The Panel recommended that AECL (or Ansell Steritech) should provide to the Health Department of Victoria details of their risk assessment and maximum credible accident evaluation and the procedures they have developed to deal with such an accident.

7.56 The Panel was advised that close liaison is maintained with the local fire brigade, who frequently visit the plant. However, the staff had not carried out any emergency exercises based on a major radiation accident. This was understandable given the safety features incorporated in the plant. Nevertheless the Panel considered that an annual emergency exercise would be valuable for the plant personnel.

7.57 Earlier this year an exercise was held to test emergency procedures at the Dandenong plant. The exercise was designed to test responses in the event of a pencil exiting the irradiation chamber. The exercise was successful in that the plant personnel evacuated the gamma radiation area very rapidly. The office staff (in an adjacent building) also evacuated their areas. All staff were assembled at the plant boundary in less than two minutes. Accounting for all personnel was completed within a further two minutes. When the alarm was activated the plant shut down automatically as required. It was estimated that the maximum exposure of staff to radiation was less than the maximum permitted exposure levels for any one year. Exposure of the public was also estimated to be within allowable limits of exposure for a member of the public.

7.58 The Committee recommends that:

the Minister for Community Services and Health request the State Ministers to require that each irradiation plant hold an emergency exercise at least every two years to test the response of plant personnel and equipment.

Transport, Handling and Disposal of Radioactive Materials

7.59 Witnesses were concerned that the operation of the present gamma radiation plants posed problems during the transport of radioactive materials. If further plants were constructed,

either for medical product sterilisation or for food irradiation, the quantities of radioactive materials being transported would greatly increase. Witnesses cited examples, including Australian examples, where there have been incidents involving quantities of radioactive isotopes being lost or involved in accidents whilst being transported. While these incidents are of concern to the Committee none of these incidents involved radioactive sources for the irradiation plants and was considered therefore outside the terms of reference of the present inquiry.

7.60 The Committee was advised that such accidents in terms of cobalt 60 could not happen. The source is carried in flasks that have been subjected to tests which simulate accident conditions, including dropping from a height of 9 metres, heating to temperatures of 800°C and involving collisions of a truck with a locomotive. Despite criticisms of the tests the Committee is satisfied that they were conducted in a manner which fairly tested the integrity of the containers. The flasks are checked by AECL personnel upon arrival in Australia and the road transport and unloading in the plant are under the supervision of AECL.

7.61 The transport of the material is subject to specific approval by State regulatory authorities on a shipment by shipment basis. It was further indicated that shipments would only occur once or twice a year at the most, even if irradiation facilities were established throughout Australia. Each shipment would be highly identifiable and subject to individual regulation, supervision and control.

7.62 The Committee was advised that there has been no leakage of radioactive material anywhere in the world from the type of container used to transport the cobalt source to plants in Australia.

7.63 Under the Commonwealth's Environment Protection (Nuclear Codes) Act 1978 the code of practice for the safe transport of

radioactive substances was promulgated. The code is based on the 1973 IAEA regulations as amended and is being revised to take account of the 1985 IAEA regulations.

7.64 Australian States have not legislated to control radioactive substances in a uniform manner although all States base their approaches on the code. Whilst the code empowers the Commonwealth to make regulations enforcing the code within a State or Territory it might be difficult for the Commonwealth to argue that a particular State's legislation did not control nuclear activities in the "manner" prescribed by the code, as this would involve a subjective judgement.

7.65 The transport of radioactive isotopes used in gamma irradiation facilities would be considered by each State as a special event and would attract special attention and appropriate international IAEA regulations would be applied. Australian State Governments advised the Committee that they have legislation which is adequate to properly regulate the transport of radioactive materials used in gamma irradiation facilities.

7.66 At present AECL is required by contract to receive back all spent radioactive sources. Concern was expressed that this arrangement was a private contract rather than an agreement between governments. It was suggested that should irradiation facilities obtain source material from other than AECL or if there is a change of Canadian Government policy there is no guarantee that Australia would not in the future be required to dispose of the spent source material itself. Victorian legislation requires that spent sources be returned to the supplier.

7.67 The Committee recommends that:

the Minister for Industry, Technology and Commerce require that the Australian Nuclear Science and Technology Organisation ensure that as a condition for the import of cobalt 60 sources the suppliers be required by contract to accept the return of expired sources.

Radioactive Sources

7.68 There are three sources used in irradiation facilities namely cobalt 60, caesium 137 and electron accelerators.

7.69 Caesium 137 is a by-product of the nuclear industry and is produced by the processing of nuclear waste. Cobalt 60 is manufactured specifically from cobalt 59 for use in irradiation facilities and is not a by-product.

7.70 Many witnesses considered that cobalt 60 was far more environmentally acceptable than caesium 137. This is primarily because cobalt is not water soluble while caesium is highly soluble. Should the stainless-steel containers holding the cobalt 60 leak there would be little effect on the water in the holding tank and it would not become radioactive. Any leakage of caesium 137 would result in the production of highly radioactive water. Should the water shielding the cobalt 60 source leak from the plant it would present no radiological hazard.

7.71 The Committee was advised of a caesium 137 leak that occurred at a medical products irradiation facility in Georgia, US on about 3 June 1988. An estimated 160 GBq of caesium leaked into the pond water. Several employees were reported as having minor skin and clothing contamination.

7.72 It was stated that while at present Australian plants and most overseas plants use cobalt 60 as the radioactive source it is probable that with increased use of ionising radiation in food and other industrial processes demand for cobalt 60 will exceed supply. This it is argued will result in the inevitable utilisation of caesium with its far higher environmental risks. Present United States supplies of caesium are fully committed. No caesium has been produced for 15 years and there are no plans for the resumption of recovery from the huge quantities of commercial

and defence nuclear waste. These plans could change if a compelling need to replenish caesium stocks was established. It seems unlikely, however, that plants in Australia which currently use cobalt would convert to the use of caesium.

7.73 The Committee received no conclusive evidence relating to the supply of cobalt 60 but Ansell Steritech advised it envisages no difficulty obtaining supplies. In addition the Company states it would not use caesium. An official of AECL told the Committee that it could meet anticipated demand. It is also likely that within 5 to 7 years efficient electron accelerators producing x-rays will have been developed and may be used in preference to isotopes for some applications. However in the view of one witness radioactive isotopes will never be replaced. For small throughputs cobalt 60 is likely to be more economic while machines may be developed which will be more economic for larger throughputs.

7.74 Many witnesses commented that the problems associated with the production, transport, use and disposal of radioactive sources would be overcome if electron accelerators were used as a substitute for radioactive isotopes. The major advantage is that no radioactive materials need to be handled and when not in use, or in the case of an accident, the machine can be turned off.

7.75 There are a number of potential disadvantages of the machine. From a practical point of view electron beams are not as penetrating as gamma radiation and therefore can only be used to irradiate the surface of the product. This has not precluded their use however in the disinfestation of grains or treatment of packaged boned chicken to eliminate salmonella. The electrons can be converted to x-rays which have similar penetrating properties as cobalt 60 radiation, however these machines consume huge amounts of electricity.

7.76 Notwithstanding these comments it is apparent that research is being undertaken into increasing the efficiency of

electron accelerators. The Manager of Ansell Steritech advised that should an economic and efficient machine source be developed the industry would rapidly convert from radioactive isotopes to machines. The other problem which has been suggested, concerning the safety of machine sources, is the need for careful calibration to ensure that energy levels remain below levels which will induce radioactivity in the product.

7.77 The relative advantages and disadvantages of the various radiation sources is shown in Table 6.

7.78 The Committee notes that any proposals to introduce machine sources of irradiation will require detailed review. Such a review will need to consider principally the question of irradiation dose control and radiation safety.

7.79 The Committee agrees with the conclusions of ACA that the environmental hazards of caesium are greater than with other sources. Because feasible alternatives are available the Committee recommends that:

> **the Minister for Industry, Technology and Commerce prohibit the import of caesium 137 for use as an irradiation source in commercial irradiation facilities.**

Mobile Irradiators

7.80 As noted in a previous chapter there are significant problems in obtaining the necessary throughput to make irradiation facilities economic. In addition it is often criticial to irradiate an agricultural product within a certain time of harvesting. One solution which has been suggested is to use mobile irradiators. AECL has developed a cobalt 60 irradiator which has been designed to meet the requirements of processing seasonal crops and produce in different geographical locations. The capacity of the automatic portable irradiator is 200 000 curies.

TABLE 6

RELATIVE ADVANTAGES AND DISADVANTAGES OF RADIATION SOURCES

Source	Advantages	Disadvantages
Cobalt-60	High penetration, good dose uniformity	12% annual decay of source
	Products of variable size, shape, and density able to be treated	Slow processing rate
	Well-established process and transported to site	Source material must be purchased overseas
	Readily available source	
	Low environmental risk	
Caesium-137	Due to its long halflife, only 2% of source needs replenishing each year	Less penetration than for cobalt-60, therefore poorer dose uniformity
	Less shielding required	Slower processing rate than for cobalt-60
	Potentially large supply	Source material must be purchased overseas and transported to site
		Higher environmental risk than cobalt-60 due to high solubility and low melting point of caesium salt used
		Production depends on reprocessing of nuclear waste
		Limited current supplies
X-Rays	No source replenishment	Complex machine
	Good penetration and dose uniformity	High maintenance requirements
	Zero environmental risk	Inefficient energy use
		Running costs high
		Operational experience limited - high output machines still under development
		Large power and cooling needs
Electron Accelerator	No source replenishment	Poor penetration and dose uniformity
	Available	Products must be of well defined thickness and density
	Established experience, particularly up to 2 MeV	Complex machine
	High throughput rate	High maintenance
	Zero environmental risk	Large power and cooling needs

Source: New Zealand Ministry for the Environment, "Food Irradiation and Industrial Radiation Processing in Ne Zealand", Feb. 1988

7.81 One witness who is an irradiation safety officer stated that he was shocked at the prospect of travelling on a highway with cobalt 60 on a season to season basis. Another witness advised that mobile irradiators would be harder to regulate than fixed irradiation facilities. She also noted that sources which are taken out into the field are possibly more hazardous than fixed irradiation sources.

7.82 The Committee received no evidence concerning the use of machine sources in mobile irradiation plants. If machine sources were used the problems associated with the transport of highly radioactive sources would not occur. Mobile machine irradiators however would present problems to regulatory authorities. There would also be the problem of proper calibration of the machine to ensure that the product was receiving the correct dose. The Committee does not support the introduction of mobile irradiators, whether or not the facility uses radioactive isotopes or machines. Accordingly the Committee recommends that:

the Minister for Industry, Technology and Commerce prohibit the import of radioactive isotopes for use as an irradiation source in mobile commercial irradiation facilities until suitable operating techniques have been developed and problems relating to regulation and safety have been resolved.

7.83 The Committee further recommends that:

the Minister for Community Services and Health discuss with State and Territory health Ministers the prohibition of the use of electron beam or x-ray machines for use in mobile commercial irradiation facilities until suitable operating techniques have been developed and problems relating to regulation and safety have been resolved.

Licensing and Environmental Assessment

7.84 The Commonwealth Government controls the importation of radioactive materials through the Customs (Prohibited Imports) Regulations (Third Schedule, Item 23). In order to obtain release of the radioactive material consignees are required to satisfy the Australian Radiation Laboratory, in the case of radioactive materials intended for medical use, or ANSTO, in the remaining cases, as the expert advisers to the Collector of Customs, that all relevant requirements, including possession of an appropriate State license, have been met. Responsibility for the standard of facilities, proposed end use of the material and disposal of the source lies with State or Territory Governments.

7.85 The Committee notes that ANSTO licenses an individual rather than a company to import radioactive isotopes. In New South Wales a person is licensed to operate the plant but the plant itself does not require a license. In Victoria legislation requires the operator to be licensed and the plant to be registered.

7.86 None of the three commercial gamma irradiation plants operating in Australia has been subject to formal environmental impact assessment. In the case of the Ansell Steritech plant at Wetherill Park in Sydney authorities did take an interest in the establishment of the plant and recommended that an ozone monitor be installed in the exhaust stack. The monitor is set to trigger at 1 part in 10^7 the threshold value level for exposure to ozone. The Ansell Steritech plant in Victoria was established before environmental assessment legislation had been enacted. In New South Wales irradiation plants are not a "designated development" under State environmental legislation and therefore do not require environmental impact statements to be prepared.

7.87 The Committee notes that a proposal by Ansell Steritech to establish a cobalt 60 plant in New Zealand has been subject to extensive environmental assessment. The Committee also notes that new rules in Canada will require a three stage approval process for the commissioning of a gamma irradiation facility. These approvals relate to the location of the plant with provision for public consultation, construction to include verification of drawings and safety provisions and an operating approval to include descriptions of personnel qualifications.

7.88 It is clear that ANSTO does not undertake a detailed assessment of the suitability of the operator or the irradiation facility when issuing permits to import radioactive materials. Provided that correctly completed applications to import the material have been lodged and are endorsed by the relevant State or Territory authority ANSTO advised that it would have no grounds to reject the application. Similarly it does not concern itself with environmental impact assessment, such as the safe location of plants, as the organisation believes this is entirely a matter for the States or Territories.

7.89 While the Committee accepts that future plants operated and designed to the standard of existing facilities should not present significant environmental hazards there are indications that approvals could be given by State authorities to locate plants in areas which may be unsuitable. To ensure that standards are maintained the Committee believes that environmental assessment which meet the conditions of the Environment Protection (Impact of Proposals) Act should be undertaken before approval is given by the Commonwealth to import the radioactive source for use in those plants.

7.90 The Committee received no evidence to suggest that the States or Territories do not have the regulations or competence to undertake the assessment process. However the Committee notes that

there have been instances overseas where operators who are clearly unsuitable have been licensed to operate plants. It is the Committee's view that before a permit is issued by the Commonwealth to allow the importation of radioactive material a detailed report (including the environmental impact assessment in the case of a new plant) on the competence of the operator be submitted to ANSTO.

7.91 Accordingly the Committee recommends that:

- **the Minister for Industry, Technology and Commerce direct the Australian Nuclear Science and Technology Organisation to ensure that before approval is granted to import radioactive sources proposed irradiation facilities be subject to an Environmental Impact Assessment which satisfies the conditions of the Environment Protection (Impact of Proposals) Act 1974 and includes an assessment of the maximum credible accident, and**

- **detailed certificates of competence of plant operators be submitted and assessed.**

Insurance

7.92 Witnesses before the Committee advised that house and property insurance policies specifically exclude damage from ionising radiation. The witnesses commented that basically the population has no insurance whatsoever against any potential danger. The New Zealand Inquiry into Food Irradiation also observed that this view was held by many.

7.93 The Committee sought information from Ansell Steritech and the Insurance Council of Australia. Ansell advised the Committee that its Company has a liability insurance cover for any accident or damage that may be caused by any of the irradiation

plants. Ansell also has insurance cover for the transportation of the radioactive isotopes. This is a double cover as AECL also is similarly insured. In addition the Insurance Council of Australia advised that normal property insurance would be available to gamma irradiation facilities.

7.94 In response to the Committee's questions relating to the exclusion clauses relating to damage from ionising radiation the Insurance Council advised that the exclusion was standard throughout all policies. However it was intended to exclude damage caused by nuclear reactors, weapons material or nuclear waste. It does not exclude damage caused by the operation of a gamma sterilisation plant or the transport of the radioactive isotopes. The Insurance Council did agree however that the clause needed to be read with some care.

7.95 While the Committee accepts that the intention of the exclusion clause might relate to only nuclear weapons, power stations and nuclear waste, it was advised that at least some individuals within some insurance companies believed that the exclusion also includes operations of gamma sterilisation plants.

7.96 Accordingly the Committee recommends that:

the Attorney-General require that standard insurance contracts be worded in such a manner as to make it clear that the policy covers damage from gamma sterilisation plants and the transport of radioactive isotopes to and from those plants.

Endnotes

1 Robotham, F.P., Advisers Report to the Committee.
2 Transcript p. 2155.
3 Robotham, Advisers Report.
4 Robotham, Advisers Report.
5 Transcript pp. 276-354.
6 Robotham, Advisers Report.

7 Transcript p. 1946.
8 Radiation Technology, Inc., Correspondence to Shareholders.
9 Robotham, Advisers Report.
10 Transcript p. 388.
11 Robotham, Advisers Report.

8. FOOD IRRADIATION REGULATIONS

Need for Federal Controls

8.1 The following discussion relates to the regulatory machinery which the Committee considers would need to be required if irradiation of food were to be approved.

8.2 The ACA concluded that if food irradiation was introduced into Australia it was essential to have a uniform and co-ordinated approach to ensure uniform standards throughout all States and Territories and to ensure the adequate quality of the process and protection and safety of the consumer and the environment. ACA believed that to achieve these objectives the Commonwealth should have the ultimate responsibility for co-ordinating and enforcing standards relating to:

- the construction of an irradiation plant;
- the operation of the irradiation plant;
- the sale of irradiated food, and
- packaging and labelling.

8.3 While not providing specific examples ACA concluded that the previous experience of relying on State legislation or relying on co-operative arrangements between the Commonwealth and the States had not been satisfactory and should not be relied upon for such a sensitive process.

8.4 In previous sections of the report relating to radiological and environmental safety the Committee has developed recommendations which would enable the Commonwealth to ensure that standards were uniform between States and in accordance with sound radiological practices. However control of licensing and operation of irradiation facilities and worker and public safety issues would remain with the States and Territories.

8.5 The Committee notes that direct Commonwealth control does not necessarily mean a higher standard. In addition the States have the necessary infrastructure to ensure day to day regulation of processes such as food irradiation. For the Commonwealth to undertake these responsibilities, apart from constitutional difficulties, it would be necessary to develop comprehensive regulatory machinery at the national level. The Chief Health Inspector of New South Wales, for example, has access to over 600 health inspectors throughout the State.

8.6 In addition each State or Territory has a radiation safety group, usually as part of the Department of Health. Such radiation safety groups are responsible for issuing radiation operator licences and overseeing the safety of radiation useage within the boundaries of their State or Territory. Those groups have both the personnel and equipment to carry out appropriate radiation monitoring.

8.7 It is the Committee's view that if food irradiation were to be approved for Australia direct day to day control should remain with the States and Territories. However this view is conditional upon uniform legislation being introduced within each State and Territory. The Committee believes that if this cannot be accomplished, rather than the Commonwealth taking over this responsibility, food irradiation should not be approved for use within Australia.

8.8 Nothwithstanding the comments made in this Chapter of the Report relating to compliance the Committee has serious reservations concerning enforcement of regulations without a routine commercial method of testing. Accordingly the Committee recommends that:

> **the Australian Government should not approve the irradiation of food in Australia until such time as a routine commercial method of detection has been developed.**

Model Food Regulations

8.9 The model food irradiation regulations formulated by the NH&MRC are at Appendix 8. In general the model regulations reflect the recommendations of the Codex Commission. The major point of difference is that the Codex standards give general approval to the irradiation of all food up to an average dose of 10 kGy. The NH&MRC regulations permit irradiation for cereals, fruit and dried fruits, poultry, herbs and spices, vegetables and dehydrated vegetables, but not fish or meat. The regulations provide for a maximum average dose of 10 kGy.

8.10 The regulations could be seen to imply a blanket approval for the irradiation of all these foods up to a maximum average dose of 10 kGy provided that the dose applied is the minimum required to achieve its purpose (clause 6(b)). On the other hand one clause of the regulations states that a person shall not irradiate food for any purpose unless the irradiation of that food, for that purpose, and the average dose of ionising radiation to be applied have been approved by the NH&MRC. It is not clear whether or not this clause relates to foods other than those approved by the regulations or whether it also applies to those approved food groups.

8.11 Given that most of the applications of irradiation can be achieved at doses less than 1 kGy and certainly below 2 or 3 kGy a blanket approval to 10 kGy appears to be unnecessary. The regulations only stipulate that the dose applied shall be the minimum that is reasonably commensurate with the technological and public health purposes to be achieved. Proponents of the process have argued that it is unnecessary to stipulate maximum doses primarily because processors would use the minimum dose applicable to achieve the desired result because of the costs involved. Secondly the food itself would dictate the limits of the irradiation dose because of unacceptable changes such as softening in fruit and changes in taste and smell.

8.12 The Committee believes that because of the nature of the technology, regulations should be drafted in a manner which specifically state the food type, the dose to achieve a desired effect and that those doses be the minimum required to achieve that effect.

8.13 The Committee notes that the Canadian regulations relating to food irradiation contain a schedule of foods permitted to be irradiated (not food classes such as vegetables or fruits), the approved sources of radiation, the purposes for which the treatment may be applied and the maximum absorbed dose permitted except in the cases of spices and dehydrated seasonings where a maximum total overall average dose is specified. To date only potatoes, onions, wheat (and wheat products), spices and dehydrated seasonings have been included in the regulations.

8.14 The regulations provide for foods to be added or changes to be made. The regulations require that submissions should include amongst other things the purpose, citing minimum and maximum doses, data indicating the effects, if any, on nutritional quality and details of any other processes which are combined with irradiation, data establishing that the irradiated food is not being significantly altered in chemical, physical or microbiological characteristics and details of storage, shipment and handling.

8.15 In the notes accompanying the Canadian irradiation regulations it is stated that the Health Protection Branch of the Department of Health and Welfare accepts in principle the lack of toxicological hazards for foods irradiated below 10 kGy. However it will examine each submission on a case by case basis to determine if additional or new toxicity testing is required. This would be of particular significance in those incidences where a food commodity which is not a member of a class of food-stuffs already subjected to extensive toxicity testing is proposed to be irradiated.

8.16 The NH&MRC model food regulations clearly require food to be irradiated in accordance with sound technological practices. They also require that doses should be the minimum required to achieve a specific effect. However the requirements appear to be statements of principle rather than detailed statutory requirements and are not as specific as those imposed by regulations which operate in Canada.

8.17 The Committee notes that it is the view of at least one State Health Department that the model regulations as presently drafted contain so many unenforceable aspects that they would be impossible for that State to adopt. It was claimed that while it may be clear to the NH&MRC what is intended, regulations must be clear, unambiguous and expressed in terms which will make them enforceable. The Committee agrees. Accordingly the Committee recommends that:

the Minister for Community Services and Health request the National Health and Medical Research Council to redraft the Model Food Standards Regulations, Section 3, Irradiation of Food, to include a specified list of food products (not classes of foods) which may be irradiated, and these foods be included in a schedule to the regulations stipulating the purpose for which irradiation has been approved and the minimum and maximum absorbed dose approved to achieve that effect.

8.18 The Committee further recommends that:

the regulations require that submissions to the National Health and Medical Research Council seeking approval to irradiate a food include:

- **details of the purpose;**
- **minimum and maximum dose;**
- **data on nutritional effects;**

- data on chemical, physical or microbiological changes;
- conditions of storage and handling, and
- details of packaging, and any other processes to be applied to the food prior to or after irradiation.

Labelling

8.19 The model NH&MRC regulations require that irradiated food be labelled in writing saying:

"TREATED WITH IONISING RADIATION"

OR

"IRRADIATED (here insert the name of the food)".

The regulations also require that if an irradiated product is used as an ingredient that this shall be declared in the list of ingredients.

8.20 The question of labelling was one of the major concerns of those who were opposed to the process. While it was argued that irradiation should not be approved for Australia it was considered essential that should approval be given consumers must be able to choose whether they wish to consume an irradiated food. While most scientists and regulatory authorities believed that food irradiation was safe they were generally of the view that such food should be labelled.

8.21 The Committee believes that the consumer should be able to clearly identify food which has been irradiated. It notes that some proponents have advocated the use of symbols without a label or discriptions such as "pico-waved" and other such titles. A witness from the NH&MRC however concluded that the product should be clearly and unambiguously labelled as irradiated.

8.22 Many witnesses were concerned that bulk foods such as potatoes or tomatoes may be in cartons which indicate that the product has been irradiated but these could be deliberately or

accidently removed from the carton. The New South Wales Department of Health believed that loose products should be individually labelled as is already common place with some fruits, or alternatively, products such as potatoes be placed in an appropriately labelled retail pack. The Department believed that the only way to ensure that consumers are not misled as to whether they are consuming irradiated food is to require that all irradiated food be packaged.

8.23 The Committee is aware that to individually mark pieces of fruit or other products as being irradiated would be costly. It notes that much loose produce is already labelled or stamped. In addition it is also accepted practice that bulky products such as potatoes are sold in retail packs. It is the Committee's view that irradiated produce should either be individually labelled as irradiated or contained in a retail pack which is labelled as irradiated. Accordingly the Committee recommends that:

- **food irradiation regulations be formulated to require that food be labelled in accordance with clause 9(a) of the National Health and Medical Research Council Model Food Standards Regulations, Section 3, Irradiation of Food, and**

- **the regulations stipulate that individual items, if sold loose, be individually labelled or stamped as irradiated.**

Packaging Materials

8.24 Some of the food which it is suggested may be irradiated will be pre-packaged before it is processed (e.g. fish and chicken). The 1964 JECFI stated that the packaging materials used as containers for irradiated foods must be subjected to careful scrutiny to ensure their suitability and safety in use. One witness advised that since that report very little attention appears to have been paid to this very important subject. He

states that while he has read a number of scientific papers on the effects of irradiation on packaging materials he has not seen one on the effects of irradiating foods in contact with packaging materials.

8.25 Major concerns about packaging include a breakdown of the packaging material which might allow contamination of the food from external sources, radiation induced changes which may make some packaging material toxic which can contaminate the food, and changes in the food and/or the packaging material which may cause chemical reactions to occur which may be toxic. The Model Food Irradiation Regulations only specify that packaging and packaging materials shall be of suitable quality. It does not detail the types of materials which should be used in the process (clause 6(d)).

8.26 The 1976 JECFI observed that methods of testing the functional properties of packaging materials and detecting migrating compounds are well established and must be applied to non-irradiated as well as irradiated packaging materials. Witnesses observed that some packaging material is clearly unsuitable for the process. In order to avoid a consumer health hazard which may originate from the break-down of the packaging material and the transfer of toxic products to the food the United States Food and Drug Administration has required that only materials for which they have issued regulations be used. Regulations also specify the maximum dose for each type of material.

8.27 The Committee believes that the packaging material used should be stipulated in the regulations. As recommended in paragraph 8.18 applications to irradiate food should contain details of the packaging material proposed. The Committee believes that in developing the packaging regulations data should be provided which indicates the results of research undertaken on the packaging material in contact with the particular food for which approval is given.

8.28 Accordingly the Committee recommends that:

the food irradiation regulations specify -

- **the packaging material which may be used during the irradiation of pre-packed foods;**
- **the type of food for which each packaging material may be used, and**
- **the maximum dose permitted for each type of packaging material.**

Repeated Irradiation

8.29 The 1976 JECFI considered that repeated irradiation of food should be avoided for a number of reasons. The evaluations of toxicological and microbiological safety and nutritional quality are in respect of foods treated within specific dose ranges of irradiation. Furthermore the product should be correctly identified to the consumer in terms of the processing to which it has been subjected.

8.30 JECFI believed that even though the concentrations of radiolytic products accumulated with repeated irradiation would be so low that the toxicological hazard likely to arise from repeated irradiation would be minimal, the food is likely to be degraded in terms of taste and nutritional quality. The 1980 JECFI concluded that in certain circumstances repeated irradiation might be justified.

8.31 The NH&MRC Model Food Irradiation Regulations prohibit the re-irradiation of foods except for foods with low moisture content that had been irradiated for the purpose of controlling insect reinfestation. They also allow for re-irradiation if they

represent less than 5 per cent of the ingredients to be irradiated. The required full dose to be applied to a food may be applied in divided doses. In no case should the accumulative overall average dose of ionising radiation of a food exceed 10 kGy.

8.32 The Committee can see circumstances where food could be re-irradiated. Spices may be irradiated for quarantine purposes and be included in a food mix which is then irradiated. In these circumstances the Committee does not consider that there would be any difficulties. However the regulations as they are presently drafted are too general. The Committee considers that the regulations should specify each food for which re-irradiation is approved.

8.33 Accordingly the Committee recommends that:

the food irradiation regulations specify -

- **individual foods which may be re-irradiated;**
- **the circumstances in which those foods may be re-irradiated, and**
- **the maximum total accumulative dose approved.**

Dosimetry

8.34 The radiation dose absorbed by a material depends on the intensity of the source, distance from the source, the time the material is exposed to radiation and the density and target thickness of the product. Radiation dosimetry is intended to provide reliable quality control of radiation processes. There are two aspects to dosimetry. First, to ensure that the product receives an adequate dose to achieve the desired purpose and ensure that the product is not over dosed and secondly, to ensure that the irradiation process is in accordance with regulatory requirements.

8.35 Witnesses advised that they doubted the capability of irradiation plant operators to accurately assess the radiation levels within the Chamber. This, it was argued, was because the cobalt 59 pencils would be charged at different levels in Canada, rods of different ages and therefore radiation intensity would be located in the irradiation chamber, some would be fully charged and others would be near the end of their economic life. This would present highly complex problems to the operator in assessing the dose which was being received by a particular product.

8.36 AECL is able to determine the specific activity of each pencil produced. The activity of each pencil is checked by radiation measurement. For any fresh pencils inserted into the irradiator source racks at the operating company's premises AECL calculates the required position of each old and new pencil in the source holding module. The Committee was advised that this is a straight forward exercise which results in a uniform dose field and which also obtains maximum useful radiation from the older cobalt pencils. In addition AECL provides the operating company with a list of conveyor timing settings needed to achieve particular doses. The production of timer settings lists is not a complex mathematical exercise.

8.37 In summary the Committee was advised that there are no major difficulties in producing uniform radiation fields of carefully known dose rates. The half life of cobalt 60 is known very accurately and it is a simple mathematical exercise to make allowance for this when calculating radiation times. Changes to operational procedures will be necessary if and when food is being irradiated. This should not present any problems as operators now have to change timer settings when materials of differing densities are being gamma sterilised.[1]

8.38 Dosimetry systems are usually classified as primary, secondary or "go/no go" types. Primary systems are accurate to within 2 to 3 per cent and are usually only used when the plant is

commissioned. Secondary systems are simpler for routine use and are accurate to within plus or minus 5 to 10 per cent. They are calibrated against primary systems. Go/no go dosimeters simply involve a colour change of a label indicating whether or not a product has received a dose somewhere within a specified dose range.

8.39 The Adelaide Group, Campaign for Nuclear Free Food (CNFF) submitted that it was clear that there is no universally accepted method of accurately determining the dose level to which food has been subjected. ANSTO acknowledges that all dosimetry systems have limitations. A single system is not available which covers the whole range of doses used for food applications. ANSTO states however that it is quite legitimate to use a dosimetry system which covers only part of the dose required and to extrapolate from the results to calculate the total exposure time needed for the material to absorb the required dose.

8.40 Another problem referred to by many groups was that food would not be evenly dosed. The outer surface would be subject to a much higher dose than the inner core of the food. Accordingly the concept of dose averaging has been developed. The CNFF submitted that dose averaging was an extremely dangerous theoretical application when applied to food and consumer health should not be put at risk by a process which was clearly still in the experimental stage.

8.41 The Burgen report stated that the ratio between the maximum and minimum doses will vary depending upon the characteristics of the radiation plant and the material being irradiated but its value would usually not be more than 2.0 while a ratio of 1.5 is a more typical figure. This means that for a sample receiving an overall average dose of 10 kGy the dose received by different parts of the sample would usually vary between 8 and 12 kGy, though in some circumstances the dose might vary between 6.5 and 13 kGy.

8.42 The Committee notes that there will be difficulty in ensuring that each part of the material receives the same dose. It has recommended in paragraph 8.17 that the regulations should stipulate the minimum and maximum dose which a product should receive. Dose ranges would be within those levels assessed as safe in toxicological and other studies. To ensure that regulatory authorities are satisfied that proper calculations have been undertaken it is recommended that:

> the Minister for Community Services and Health request State Ministers to ensure that before the commencement of operations, in the case of a new plant, and after the loading of fresh sources or other modifications in an existing plant, any company carrying out food irradiation provide State regulatory authorities with:
>
> . details of radiation field strength and dose contours;
>
> . details of proposed radiation times for the different foods to be irradiated, and
>
> . details of dose controls to be used, such as type of dosimeter.

Compliance

8.43 One author observed that from a regulatory point of view it is desirable to have available an objective test procedure to identify a food as having been irradiated. In addition it would be desirable to have a means of measuring the applied dose. He concluded that there is no reliable and otherwise satisfactory analytical procedure for the identification of the food as having been irradiated nor is there any means of establishing the dose employed. While certain changes in foods resulting from irradiation have been identified there is no specific change which can serve as a regulatory need.[2]

8.44 The 1976 JECFI commented that the search for methods that permit the identification of irradiated foods is not without scientific interest but the availability of such methods should not be made a condition for permitting food irradiation or trade with irradiated foods. JECFI commented that food irradiation can not be done in a clandestine fashion.

8.45 Comments made to the Committee indicated that JECFI's conclusion relating to clandestine irradiation of food are not necessarily borne out by facts. While it cannot be proven, it is possible that some irradiated spices and prawns have been "inadvertantly" imported into Australia. It was also suggested by one witness that one company was offering gamma sterilisation as a service and another may have been irradiating spices for inclusion in a prepared food product. Another witness referred to instances overseas where produce had been illegally irradiated to reduce bacterial contamination.

8.46 One witness observed that he finds it somewhat bizarre that after nearly 70 years of experimentation to determine the safety of irradiated foods nobody thought to ask what would actually happen to safety in the real world of international trade. The fact that irradiation destroys bacteria was seen only as a benefit. He claimed that the "bug count" is the principal method by which regulatory authorities determine whether food is wholesome, and is used by quarantine and public health agencies. The witness advised that this has serious health implications as only kills the bacteria and not the bacterial toxins.

8.47 The Tasmanian Branch of the Australian Institute of Health Surveyors, whose members are responsible for ensuring compliance with food regulations, stated that because there are no routine tests health inspectors would find it extremely difficult to enforce the regulations. The witnesses commented however that similar problems are encountered with other processes, such as

canning, where on site inspection is required to ensure compliance with regulations. The head of the New South Wales food inspection service advised that irradiation presented no unique problems.

8.48 A range of methods for the detection of irradiated food is currently under investigation. It is unlikely however that one method will be applicable to all foodstuffs. It appears that electron spin resonance (ESR) is one of the most promising. ESR measures free radical activity in irradiated foods. It is not suitable for moist foods because the radicals quickly combine to form stable products. On the other hand, samples containing bone or other calcified tissues, such as shells of molluscs or crustacea, show an ESR signal that is both stable and characteristic of irradiation. It was claimed that it is even possible to determine the dose at which the product has been irradiated. Further work is required and there is still some doubt that the results of this type of analysis are accurate or predictable enough to be enforceable in a court of law.

8.49 It appears at this stage that the only means to ensure compliance with regulatory controls will be by plant inspection. As stated previously this is not unique to irradiation and other forms of food processing are regulated in a similar manner. However food irradiation in Australia is an entirely new food process and it is therefore essential that a routine means of detection be developed for regulatory purposes.

8.50 The British Government, while accepting that the process is safe, has maintained its ban on irradiated food until such time as a routine method of testing has been developed.

8.51 To ensure that the regulations are not accidentally (if not deliberately) breached extensive documentation has been required by overseas legislation. The Canadian legislation, for instance, requires that a manufacturer who sells a food that has been irradiated must keep his records for at least two years after

the date of the irradiation. Records containing specified information must be kept by those who import irradiated food. The NH&MRC Draft Food Irradiation Code requires similar records to be kept.

8.52 The Committee recommends that:

food irradiation regulations be drafted to require extensive records to be kept in accordance with the National Health and Medical Research Council Model Food Standards Regulations, Section 3, Irradiation of Food, clauses 8 and 10.

8.53 The Committee further recommends that:

food irradiation regulations include specific provisions to enable public health authorities free access to irradiation facilities and their records.

8.54 The Committee notes the concern of many about the ability of regulatory authorities to ensure that illegal irradiation does not occur. The Committee accepts that regulation may be more difficult than for some other food processes. Accordingly it believes that penalties for non-compliance with the regulations should be severe enough to discourage deliberate breaking of the law.

8.55 Accordingly the Committee recommends that:

food irradiation regulations contain penalties sufficiently severe to ensure compliance.

General Agreement on Tariffs and Trade (GATT)

8.56 Many witnesses commented that while it is possible for Australia to regulate to prevent food irradiation or require food irradiation to occur under specified conditions the General

Agreement on Tariffs and Trade will make it extremely difficult for Australia to refuse the importation of irradiated foodstuffs.

8.57 The Committee was advised that GATT has specific provisions allowing countries to introduce measures preventing the import of products which it considers may be harmful to human, animal or plant life or health. In the case of irradiated food, if Australia determined that food irradiation posed a health risk, banned imports of all irradiated foods from all sources and prevented domestic sales of irradiated food, it is probable that Australia would be considered to have met the provisions of GATT.

8.58 In addition it appears that Australia could approve irradiation for export purposes but not for domestic consumption to any country willing to accept it without contravening the GATT obligations. The Committee is of the view that such export approval would be hard to justify to the international community on ethical grounds.

8.59 It appears nevertheless that provided Australia does not impose restrictions on the import of produce that differ in any manner from conditions which will apply within Australia the import of irradiated products can be controlled. If a dispute were to arise regarding the consistency of Australian action with the provisions of GATT the dispute settlement provisions of GATT are such that a decision on consistency would be taken by the GATT contracting parties, following investigation by an impartial panel.

PETER MILTON
Chairman

November 1988

Endnotes

1 Robotham, F.P., Advisers Report to the Committee.
2 Urbain, W., Food Irradiation, Academic Press, 1986, p. 286.

APPENDIX 1

LIST OF WITNESSES

Attwood, Mr B.S.	Chairman, Medical Advisory Panel, Hyperactivity Association of South Australia Inc.
Attwood, Mrs E.J.	Research Officer, Hyperactivity Association of South Australia Inc.
Baghurst, Dr K.	Principal Research Scientist, Division of Human Nutrition, Commonwealth Scientific and Industrial Research Organization
Bailey, Mr C.R.R.	President, International Association of Cancer Victims and Friends
Baker, Dr C.	Executive Director, Public Health Service, South Australian Health Commission
Bell, Mrs F.J.	Research Officer, Federated Association of Australian Housewives (Tasmania)
Berson, Ms L.T.	Senior Policy Officer, Department of the Premier and Cabinet (Western Australia)
Birks, Mr P.R.	Principal Plant Standards Officer, Department of Agriculture (South Australia)
Bloomfield, Ms L.	Co-ordinator, People Against Food Irradiation
Boag, Dr T.S.	Lecturer, Riverina-Murray Institute of Higher Education
Bowen, Mr D.T.	Representative, Insurance Council of Australia
Brain, Mr S.V.F.	Representative, Member Company, Insurance Council of Australia
Brooks, Ms N.	Member, Brunswick Community Health Service
Brown, Mr R.	Director, Australian Federation of Consumer Organisations
Browning, Dr A.J.	Private Citizen
Cetinic-Dorol, Mr L.	Administration Officer, City of Cockburn
Clayton, Dr G.	Convenor, Movement Against Uranium Mining
Coleman, Mr D.J.	State Secretary, Australian Institute of Health Surveyors (Tasmanian Division)
Cooper, Dr R.	Reader in Physical Chemistry, Department of Chemistry, University of Melbourne

Corkill, Mr J.R.	Deputy Chairperson, Nature Conservation Council of New South Wales
Coulter, Dr J.R.	Vice-President, Conservation Council of South Australia
Court, Ms B.A.	Private Citizen
Cousins, Mr I.H.	Assistant Secretary, Nuclear Policy Branch, Department of Foreign Affairs and Trade
Coutts, Mr R.D.	Manager, Queensland Horticultural Export Development Service, Committee of Direction of Fruit Marketing
Crothers, Mr N.	Technical Manager, Australian Consumers Association
Crouch, Dr P.C.	Senior Scientific Officer, Radiation Control Section, South Australian Health Commission
Cumming, Dr F.J.	Member, Dietitians Association of Australia
Dahl, Dr C.J.	Australian Government Analyst, Australian Government Analytical Laboratories, Department of Administrative Services
Dale, Ms L.	Member, Citizens Concerned about Food Irradiation
Dalins, Mr J.	Principal Chemist, Australian Government Analytical Laboratories, Department of Administrative Services
Davidson, Miss S.K.	Private Citizen
Dean, Mr J.H.	Acting Assistant Director, Australian Quarantine and Inspection Service, Department of Primary Industry
Douglas, Mrs M.J.	Research Officer, Federated Storemen and Packers' Union
Dreosti, Dr I.E.	Senior Principal Research Scientist, Division of Human Nutrition, Commonwealth Scientific and Industrial Research Organization
Dryden, Mr P.	Major Hazards Unit, Department of Environment and Planning (New South Wales)
Edwards, Prof. R.	Chairman, Food Standards Committee, National Health and Medical Research Council
Erwin, Mr L.	Principal Executive Officer, International Programs, Australian Quarantine and Inspection Service, Department of Primary Industry
Evans, Dr R.A.	Private Citizen
Faigl, Mr P.	Private Citizen
Field, Miss S.	Member, People Against Food Irradiation

Finkel, Mr M.	Private Citizen
Fitch, Mrs J.	Immediate Past President, Australian Radiation Protection Society
Fleischmann, Mr A.W.	Officer in Charge, Radiation Health Services, Department of Health (New South Wales)
Forsyth, Dr J.R.L.	Director, Microbiological Diagnostic Unit, University of Melbourne
Fricker, Ms A.M.	Member, Campaign for Nuclear Free Food (South Australia)
Friend, Mr J.A.	Research Officer, Citizens Concerned about Food Irradiation
Friend, Mr R.K.	Treasurer, Allergy Recognition and Management Inc.
Gallop, Mrs K.	Co-ordinator, Campaign Against Food Irradiation
Geard, Mr I.D.	Assistant Director, Plant Services, Department of Agriculture (Tasmania)
Hancock, Ms S.	Representative, Kentish Peace Group
Hardy, Dr C.J.	Chief, Isotope Division, Australian Nuclear Science and Technology Organisation (Australian Atomic Energy Commission)
Harris, Dr A.W.	Research Scientist, Walter and Eliza Hall Institute of Medical Research, Royal Melbourne Hospital
Hayter, Mr R.L.	Assistant Director, Health Surveying Services, South Australian Health Commission
Herbert, Ms H.	Member, Citizens Concerned about Food Irradiation
Hill, Mr G.A.	Director, Nuclear Food Irradiation Campaign, Greenpeace Australia Ltd
Hill, Mrs M.	Secretary, Campaign for Nuclear Free Food (South Australia)
Holmes, Dr M.	Consultant, Walter and Eliza Hall Institute of Medical Research, Royal Melbourne Hospital
Holt, Mr B.O.	Executive Director, Grocery Manufacturers of Australia Ltd
Hoystead, Mr P.	Director, Tasmanian Conservation Trust Inc.
Hunter, Dr C.R.	Senior Lecturer, Anatomy Department, Faculty of Medicine, Monash University
Jackson, Mr M.	Principal Food Scientist, Health Department (Western Australia)
Jakobsen, Ms C.A., MP	Federal Member for Cowan
Jefferies, Mr M.G.	Principal Science Administrator, Plant Quarantine and Inspection Branch, Department of Primary Industry
Johnson, Mr G.K.	Assistant General Secretary, Federated Storemen and Packers' Union

Julius, Mr H.	Technical-Scientific Research Officer, Citizens Concerned about Food Irradiation
Kidd, Mr D.W.	Chairman, Committee of Direction of Fruit Marketing
Kinsella, Mr M.N.	Manager, Plant Standards Branch, and Chief Plant Quarantine Officer, Department of Agriculture and Rural Affairs (Victoria)
Koeyers, Mr J.E.	Private Citizen
Kucina, Mr S.J.	President, Organic Gardening and Farming Society (Tasmania)
Lamb, Mr B.	Organiser, Campaign for Nuclear Free Food (South Australia)
Lamb, Mr I.D.	Acting Assistant Secretary, Environment Assessment Branch, Department of Arts, Heritage and Environment
Laurence, Dr G.S.	Department of Physical and Inorganic Chemistry, University of Adelaide
Lawrence, Mr M.J.	Federal Research Officer, Federal Council of the Food Preservers Union of Australia
Lokan, Dr K.H.	Chairman, Radiation Health Committee, National Health and Medical Research Council, and Director, Australian Radiation Laboratory
Lowe, Dr I.	Honorary Consultant, Australian Federation of Consumer Organisations
Lowe, Prof. I.	Council Member, Australian Consumers Association
Maisch, Mr D.R.	Researcher, Tasmanian Conservation Trust Inc.
Mamers, Dr H.	Private Citizen
Marks, Ms I.	Spokesperson, Friends of the Earth
McAllister, Mr G.A.	Member, Friends of the Earth
McCluskey, Dr J.	Senior Lecturer in Immunology, Department of Pathology and Immunology, Monash University
McEgan, Mrs C.C.	Chairwoman, Board of Directors, Greenpeace Australia Ltd
McGilchrist, Mr E.J.	President, Sunshine Coast Fruit and Vegetable Growers Council
Melbourne, Mr A.J.	Acting Chief Radiation Officer, Radiation Safety Section, Health Department (Victoria)
Miller, Mr E.	Spokesperson, Friends of the Earth
Miller, Mr I.C.	Senior Microbiologist, Australian Government Analytical Laboratories, Department of Administrative Services
Mills, Mr R.J.	Committee Person, Campaign for Nuclear Free Food (South Australia)

Moore, Dr R.C.	Scientific Officer, Laboratory Research Division, Peter MacCallum Cancer Institute
Mountwinter, Mrs J.L.	Co-ordinator, People Against Food Irradiation
Murphy, Dr G.J.	Assistant Secretary, Food and Environmental Protection Branch, Department of Health
Murray, Dr D.R.	Australian Conservation Foundation Representative to the Consumers' Health Forum
Neale, Mr J.R.	Managing Director, Hartfield Pty Ltd
Nestel, Dr P.J.	Chief, Division of Human Nutrition, Commonwealth Scientific and Industrial Research Organization
Newton, Mr R.A.	Acting Director, Nuclear Affairs Section, Nuclear Policy Branch, Department of Foreign Affairs and Trade
O'Brien, Miss C.	Veterinarian, Walter and Eliza Hall Institute of Medical Research, Royal Melbourne Hospital
Oldroyd, Mrs J.D.	Foundation Member, Mothers Against Food Irradiation
Osiecki, Mr H.	Vice-President, College of Dietitian-Nutritionists in Private Practice
Palmer, Miss N.H.	Senior Nutritionist, Nutrition Section, Department of Community Services and Health
Peters, Dr F.E.	Private Citizen
Phillips, Mr C.H.	Foundation Member, Citizens Concerned about Food Irradiation
Phillips, Ms M.L.	Member, Friends of the Earth
Quail, Mr R.R.	Co-Secretary, Campaign for Nuclear Free Food (Victoria)
Robotham, Mr F.P.J.	Private Citizen
Rolland, Mr J.M.	Head, Technical Secretariat, Australian Nuclear Science and Technology Organisation (Australian Atomic Energy Commission)
Ross, Dr J.A.	Nuclear Section, Environment Co-ordination Branch, Department of Arts, Heritage and Environment
Rouch, Dr G.J.	Chief Health Officer, Health Department (Victoria)
Sands, Mr J.R.	Assistant Secretary, Environment Co-ordination Branch, Department of Arts, Heritage and Environment
Sangster, Mr D.F.	Royal Australian Chemical Institute
Scott, Mr J.L., MP	Federal Member for Hindmarsh
Seberry, Mr J.A.	Principal Officer, Plant Production Research, Department of Agriculture (New South Wales)

Sertich, Ms M.	Committee Member, Campaign for Nuclear Free Food (Victoria)
Sibraa, Mr D.N.	Chief Food Inspector, Department of Health (New South Wales)
Smith, Mr A.J.	Research Officer, Australian Federation of Consumer Organisations
Smith, Mr N.W.	General Manager, Committee of Direction of Fruit Marketing
Smith, Ms P.J.	Manager, Public Affairs, Australian Consumers Association
Sourile, Ms D.	Acting Secretary and Media Co-ordinator, Citizens Concerned about Food Irradiation
Strong, Rev. M.	Archdeaconess, Orthodox Catholic Church
Stynes, Dr B.	Director of Horticulture, Department of Agriculture (Western Australia)
Sutherland, Dr G.R.	Chief Cytogeneticist, Adelaide Children's Hospital
Sutherland Smith, Mrs B.	Committee Member and Media Representative, Campaign for Nuclear Free Food (Victoria) and Spokesperson, National Coalition to Stop Food Irradiation
Sweeney, Mr D.	Co-ordinator, Anti-Uranium Collective, Friends of the Earth
Taylor, Dr M.E.	General Practitioner
Troup, Dr G.J.F.	Reader in Physics, Physics Department, Monash University
Tugwell, Mr B.L.	Senior Research Officer, Postharvest Horticulture, Department of Agriculture (South Australia)
Von Witt, Dr V.	Private Citizen
Wahlqvist, Prof. M.L.	Head of Medicine, Department of Medicine, Monash University
Warth, Ms K.	Treasurer, College of Dietitian-Nutritionists in Private Practice
Webb, Mr T.	Consultant, London Food Commission
West, Mr G.C.	General Manager, Ansell Steritech
Wilkinson, Mr K.W.	Assistant Secretary (GATT), Multilateral Trade Division, Department of Foreign Affairs and Trade
Wills, Miss P.A.	Senior Principal Research Scientist, Australian Nuclear Science and Technology Organisation (Australian Atomic Energy Commission)
Wilson, Mr J.A.	Assistant Manager, Queensland Horticultural Export Development Service, Committee of Direction of Fruit Marketing

Wood, Mr J.M.	Associate Member and Practising Health Surveyor, Australian Institute of Health Surveyors (Tasmanian Division)
Young, Ms D.	Foundation Member, Coalition for Safe Food

In addition, the Committee received written evidence from academics, Commonwealth and State Government Departments and Authorities, community organisations, industry, primary producer organisations, private citizens and unions.

APPENDIX 2

INDUCED RADIOACTIVITY

In addition to the ionising energy released from naturally radioactive elements, humans nowadays are exposed to ionising radiation resulting from human activities. The several sources are discussed in the following paragraphs.

The detrimental effects of excessive doses of ionising energy on human health have been known for many years. Hence, the possible uses of ionising energy for the benefits they may confer have long been subject to careful scrutiny.

Miscellaneous Sources

The major use of induced ionising radiation is in x-rays for medical and dental diagnosis and treatment. The average human exposure from this source is equivalent to about 40% of the background radiation. Minor sources include the nuclear power industry, which results in a human radiation dose less than 0.4% of the natural background ionising radiation. The dose from aviation is equivalent to about 0.4% of the natural background ionising radiation, and the dose from the fossil fuel industry is equivalent to about 0.04%. (Aviation is a factor because radiation received from extra-terrestrial sources increases with altitude as a result of the reduced thickness of the protective layer of air.)

The fallout of radioactive materials from nuclear explosions in the atmosphere peaked in 1963. At that time, the ionising energy emitted from this source amounted to about 13% of the natural background in the United States. This contribution has steadily decreased since most of the testing in the atmosphere was stopped in 1962, and it is now less than 4% of the natural background (Anonymous, 1980).

Food Processing

A fundamental premise in the use of ionising energy for food processing and pest control in foods is that it must contribute no measurable amount of radioactivity to the food treated. Radioactivity can be induced if the energy level is great enough. As a result of extensive research on this subject, the Joint Expert Committee on Irradiated Foods of the Food and Agriculture Organization of the United Nations (FAO), the International Atomic Energy Agency (IAEA), and the World Health Organization (WHO) (WHO, 1965, 1981b) recommended 10 million electron volts as the maximum permissible energy for electron generators and 5 million electron volts for x-rays. These maximum energy levels are accepted by health authorities in the United States (FDA, 1984) and by the international Codex Alimentarius Commission (CAC, 1984). According to the Joint FAO/IAEA/WHO Expert Committee (WHO, 1965), these energy limits are conservative, and in special cases

it may be reasonable to permit slightly higher limits. The Joint FAO/IAEA/WHO Expert Committee did not specify a maximum energy level for gamma rays because neither of the two approved sources (cobalt 60 and caesium 137) induces measurable radioactivity in food at any dose. The energy levels of the gamma rays from these sources are 1.33 million electron volts for cobalt 60 and 0.66 million electron volts for caesium 137.

Experimentally, no measurable radioactivity was induced in chicken meat products processed with electrons at energies of 10 million electron volts at doses as great as 68 kilograys in the U.S. Army-USDA wholesomeness studies. No measurable radioactivity was induced in beef sterilised with 71 kilograys of ionising energy.

The sensitivity limit in the best direct measurements is usually about 1% of the natural radioactivity in the food; that is, the minimum increase in radioactivity that can be detected reliably in direct measurements is about 1% of the natural radioactivity. Estimates that provide far greater sensitivity have been made in special indirect ways. A study indicates that the maximum level of ionising energy recommended by the Joint FAO/IAEA/WHO Expert Committee (10 million electron volts) resulted in an estimated increase in radioactivity of a disintegration of one atom per week per kilogram of meat in comparison with a disintegration of more than 100 naturally radioactive atoms per second per kilogram of meat and compared with a disintegration of about 10,000 naturally radioactive atoms per second in the average human body weighing 70 kilograms (or more than 140 disintegrations per second per kilogram of human tissue). The estimated increase in radioactivity of meat resulting from radioactive fallout amounted to 10 atomic disintegrations per second per kilogram of meat.

The increased risk of cancer from the induced radioactivity caused by treating meat with accelerated electrons thus is negligible. If the same linear extrapolation that was used to obtain an estimate of an increase of 0.3 to 1% of the cancers from natural background ionising energy is used to estimate the contribution of the induced radioactivity of food to human cancer, one finds that the contribution amounts to 0.000000003 to 0.00000001%. This assumes that all food has the same natural radioactivity as meat and that all food is processed with the maximum permissible energy at sterilizing doses.

Source: Council for Agricultural Science and Technology

APPENDIX 3

ALTERNATIVES TO FOOD IRRADIATION

During the presentation of their evidence to the Committee the People Against Food Irradiation (PAFI) group submitted a number of possible alternatives to food irradiation which they believe could be considered. The Committee of Direction of Fruit Marketing (COD) responded to these suggestions.

Heat and cold treatment

This involves harvesting fruit at one quarter ripeness and dipping it in hot water, followed by cold treatment, or alternatively, harvesting one quarter ripe fruit and then subjecting it to double dip in hot water.

The double dip hot water treatment has been accepted, only by mainland US for certain products. The US has reported many quality problems which are said to result from early harvesting. Japanese quarantine authorities do not accept that double hot water dip treatments confer an appropriate level of quarantine protection and security.

Cold storage treatments are already used as widely as practicable in Australia for the purpose of disinfestation. However the treatment is limited in its application by the cold tolerance of the product at temperatures lethal to insects. Some products suffer chilling injury which render them unmarketable. Japanese quarantine authorities will not accept the shipboard disinfestation of produce from Australia. However the practice is permitted for produce from the US.

Sterile insect release process

This involves breeding and releasing of sterile insects, resulting in non reproduction of that particular species. Fruit fly control programs have been shown to be workable alternatives to ethylene dibromide.

This is a component of some pest eradication programs leading to the status of "area freedom" from the pest concerned. Areas granted this status may export produce to the designated market without treating the produce for the insect pest concerned. Parts of Australia already have area freedom status and the sterile insect technique has been used in WA against Mediterranean Fruit Fly, an introduced pest. This method has been appraised for Queensland by scientific authorities and considered inappropriate because of the dispersal of Queensland fruit flies in natural wilderness areas. The method relies on trapping to monitor eradication effectiveness and lures are still lacking for some of the native fruit fly species. Work is still continuing in this area.

Development of disease/insect resistant plants

CSIRO has been conducting research into this area.

Disease resistance is more readily selected for in a plant breeding program than is insect resistance. This should be a long term consideration in all such programs but, regrettably, the success rate is very low even for diseases.

Modified atmosphere treatment

This process is suitable as a substitute for ethylene dibromide fumigation on grains to reduce insect infestation. Blasting of carbon dioxide or nitrogen kills the insects by depriving them of oxygen.

These techniques are already used extensively in the stored grain industry. For fruit and vegetables they are generally unsuitable because of the extended time taken to kill insects. There are complications for fruit when latent fungal infections are favoured by the modified atmosphere.

Aluminium phosphide treatment

This is a known safe alternative to ethylene dibromide fumigation in the US.

This fumigant, also known as phosphine, is widely used for disinfestation of grain. Research has shown it to be inappropriate for use on fruit against the Queensland Fruit Fly due to the damage caused to fruit at the doses required to kill the fly and the slow mode of action which requires sealing the produce for five days, followed by five days airing to disperse residual gas.

Heat sterilisation of herbs and spices

This process involves heat sterilisation with super heated steam.

Most fruits are damaged by more than a very brief time at 52^{o}C. Superheated steam would obviously be inappropriate for fruit and vegetables.

Microwave and infra-red treatment

As an alternative to the use of ethylene dibromide on stored grain microwaves to heat the grain under vacuum conditions have been used. This technique is ready for commercialisation. Heat treatment by infra-red also appears to be feasible and effective.

Early research showed these methods to have no application to fruit and vegetables for disinfestation purposes.

Sonar detection

A device called an "acoustic coupler", which can detect fruit fly larvae by the vibrations caused when the larvae eat the fruit, has been developed. Infested fruit is then removed before it is shipped.

This technique is technologically complex and still at a very early stage of development. It is theoretically desirable but will require costly refinement to develop it. The capital cost could prove to be very substantial for a central packing facility and totally uneconomic for on-farm application.

Cold storage

Increase the facilities currently available for cold storage, develop lower cost storage facilities and ensure that cold storage facilities have uniform controlled temperature mechanisms.

This facility is widely developed, down to the level of individual growers.

Better marketing strategies

Implement improved crop sowing methods to prevent over supply and plant crops at different periods to prevent simultaneous ripening.

COD is considered the industry leader in this field, with large amounts of time and money invested in promotion and marketing.

Multitherm preservation

The "multitherm" process involves rapid but even heating throughout the food. After packing the food in a plastic container, it is pre-heated, then briefly cooled, and then surrounded in a water bath and heated in a microwave oven. Finally the product is cooled to room temperature and can be stored in this state for several months. This technique does away with canning and obviates the need for freezing food. It rivals canning in its low cost and products taste fresh, even for difficult to preserve foods such as fruit and vegetables.

This technique is not appropriate to fruit and vegetables at the scale and volumes required for export marketing. The temperature aspects of the technique render it unsuitable for tropical and sub-tropical products. Cost would be a significant factor against it.

Comparative costs

It has been estimated that application of irradiation to food items will increase the cost.

Given that disinfestation treatments are essential to comply with quarantine requirements of markets, the cost of irradiation is estimated to be very comparable to EDB fumigation.

Subsequent to the above evidence PAFI provided the Committee with the following additional alternatives to food irradiation. COD or other witnesses did not have the opportunity to respond to these new processes.

Semperfresh

This is a process which uses pure sucrose esters (a derivative of sugar) as a coating on fruit and vegetables to delay ripening and extend shelf life.

Semperfresh is derived from pure food ingredients and is edible and bio-degradable. It is produced as a powder which is dispersed in water for use. When coated on the outside of fresh fruit it has the property of delaying ripening. It reportedly has been approved for use by the FDA and other international bodies.

Hydroponics

This is an application for growing fruit and vegetables and flowers in washed gravel. The produce is grown in washed gravel and enclosed in a large plastic dome. The advantages are freedom from pests and diseases, easy harvesting and large crop yields from small areas of land.

Sterispice

This is a process which utilises a pre-determined thermal sterilisation cycle combined with a coating process for sterilising herbs and spices in their original form. The disadvantages are that due to high temperatures and moisture some spices darken and there is a small loss of flavour components. The advantages are that it reduces the bacterial count to practically zero and reduces or eliminates enzyme activity.

Dry heat treatment

This is a treatment using hot forced air to disinfest fruit fly in papayas and other tropical fruits.

APPENDIX 4

AN ANALYSIS OF THE SAFETY OF FOOD IRRADIATION: GENETIC EFFECTS

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A report prepared for the House of Representatives Committee on the Environment, Recreation and the Arts, November 1988.

The Issues

A major concern of opponents of food irradiation is whether it is safe to consume irradiated food. No evidence of acute toxicity from the consumption of irradiated food has been uncovered so a major concern is that life-long consumption of irradiated food may lead to the ingestion of small quantities of potentially harmful radiolytic products which may accumulate in the body and thereby produce long-term adverse effects.

Three main concerns have been expressed about long term safety in the critical literature (e.g. Australian Consumers' Association, 1987; Julius, 1988; Webb and Lang, 1987). The first concern is that irradiation may produce radiolytic products in food which, if consumed in sufficient quantity, may produce changes in human genetic material (e.g. Webb and Lang, 1987), and that these changes may, in turn, lead to cancer (if the cells affected are somatic cells), or to genetically transmitted defects (if the cells affected are germ cells).

A second concern is that the process of irradiation may deplete foods of essential nutrients. Although it is conceded that this may not be a serious problem for well-nourished persons, the concern is that people whose diet is marginal, and in whom irradiated foods comprise a substantial component of the diet, may develop deficiency diseases, or a reduced resistance to infectious disease (e.g. Julius, 1988; Webb and Lang, 1987). This concern is not shared, however, by professional nutritionists who, in submissions to the Committee, have made worst case estimates

of the impact of irradiated food on the vitamin intake in the average Australian's diet and concluded that its impact will be minimal.

A third concern is with the microbiological safety of food irradiation. This covers a number of issues. One fear is that irradiation may kill harmless bacteria which provide the usual indications of food spoilage (smell, taste and appearance), thereby allowing harmful microorganisms (e.g. botulism) to grow undetected. Another is that irradiation may produce mutations in pathogenic microorganisms (e.g. *Aspergillus flavus*) which may be found in certain foods (e.g. grains and nuts). The fears here are that (i) these and other microorganisms may become radiation resistant and (ii) that irradiation of toxin-producing fungi may cause them to produce increased levels of toxins (e.g. aflatoxins) thereby increasing the likelihood of human diseases being caused by these microorganisms (Julius, 1988; Webb and Lang, 1987). Few, if any microbial geneticists share these concerns (see, for example, Forsythe, 1988).

We will therefore concentrate on the first issue in this report. Does the long term consumption of irradiated food increase the risk of occurrence of delayed genetic effects such as cancer in the case of the person consuming the food, or inherited birth defects in the case of the progeny of persons who consume the food?

Principles in the Evaluation of Safety

It is necessary to agree upon some general principles for evaluating the safety of any changes in a process which impinges upon human well-being to the extent that food irradiation might. Two separate issues need to be resolved: (1) where does the burden of proof lie, with those who argue that it is safe, or with those who argue that it is unsafe? and (2) by what standard will the claims of contending parties be evaluated? Answers have been implicitly given to both questions by opponents of food irradiation who assume that advocates of the process have an obligation to prove that it is safe beyond reasonable doubt, and hence that any doubt about the safety of food irradiation should be resolved by deciding against its introduction.

We would suggest that if the Committee decides that the burden of proof lies with those who would introduce food irradiation, then it should adopt a reasonable standard of proof. We would suggest the following principles: that the opponents of food irradiation have to provide a prima facie case for the process being dangerous, whereas proponents need to demonstrate that the process does not cause any of the adverse effects identified by its opponents. Any requirement that the process be safe beyond all doubt sets too high a standard, one that can be satisfied rarely, if at all, and one that must be selectively applied to new rather than to existing methods of food processing.

We suggest that those who claim that the consumption of irradiated food is a cause of genetic damage need to provide evidence:

(1) that animals fed on a diet of irradiated food have a higher rate of genetic damage than animals fed on non-irradiated food; and

(2) that there are good biological reasons for believing that the relationship is truly causal, that is, it cannot be explained in any other way.

We suggest that those who claim that the consumption of irradiated food does not cause genetic damage need to provide evidence:

(1) that animals fed on a diet of irradiated food do not show a higher rate of genetic damage than animals fed on non-irradiated food; such evidence should come from studies which have a good chance of detecting such an effect if one exists; and

(2) that there are good biological reasons for not expecting such a relationship, for example, the absence of a plausible mechanism, based upon a detailed understanding of the underlying biological processes which make the relationship an improbable one.

The disciplines of experimental design and statistical inference provide formal criteria for evaluating the adequacy of evidence in favour of the first requirement. In the case of both opponents and proponents of food irradiation these include:

(i) the requirement that animals are randomly assigned to receive either irradiated or non-irradiated food in order to minimise pre-existing differences between the animals in each condition (Fisher, 1949);

(ii) the use of reliable and valid measures of genetic damage, i.e. measures which show genetic change if it occurs, and not otherwise;

(iii) an appropriate form of statistical analysis of the data to make the hypothesis of chance an unlikely explanation of the data;

(iv) the requirement that independent researchers are able to replicate the results of the study, i.e. to obtain the same results when they repeat the experiment.

(v) in the case of studies which fail to find a a difference between animals fed on irradiated and nonirradiated food, a statistical power analysis (Cohen, 1977) is essential to demonstrate that the studies had a good chance of detecting a difference if one existed.

Expert biological knowledge about the mechanisms of genetic damage is required to evaluate the second criterion - the biological plausibility of a causal relationship, or its absence. Only someone with expert knowledge in genetics can answer the following questions: Are the measures of genetic damage (e.g. polyploidy in peripheral lymphocytes) valid and reliable? Are there any errors in experimental technique that invalidate the results? Do they results make genetic sense, i.e. are they the type of effects one would expect if food irradiation caused genetic damage ?

DOES IRRADIATED FOOD CAUSE GENETIC DAMAGE?

An evaluation of the claim that the consumption of irradiated food causes genetic damage requires an analysis of the evidence in favour, and the biological plausibility of, each step in a complicated causal chain involving at least six steps. These are that:

(i) irradiation produces genotoxic products in food which,

(ii) persist in the food long enough,

(iii) to be absorbed in sufficient quantity by the organism

(iv) to reach the DNA in the cell nucleus in their genotoxic form

(v) producing genetic damage in the DNA of exposed cells which can be converted from pre-mutagenic damage to fixed mutations,

(vi) and that any such cells either become cancerous, or else, because the changes in the DNA occur in germ line cells, are then transmitted to the next or subsequent generations.

We can evaluate this claim in two steps. First, we can ask the question: does genetic change occur at a higher rate among animals which have consumed irradiated food? If it does not, the causal claim is seriously weakened. Second, if there is no relationship between the consumption of irradiated food and genetic change, the case in favour of rejection is strengthened by showing that one or more of the events that are assumed to occur in this chain of occurrences are extremely unlikely to occur. Since a causal chain is only as strong as its weakest link, the more weak

links there are in the alleged chain, the more improbable the causal claim which is based upon it.

THE NATIONAL INSTITUTE OF NUTRITION STUDIES

The opponents of food irradiation who argue that food irradiation may cause genetic damage (e.g. Tritsch, 1988; Webb and Lang, 1987) cite evidence from a series of studies undertaken at the National Institute of Nutrition in India in the 1970's (Bhaskaram and Sadasivan, 1975; Vijayalaxmi and Sadasivan, 1975; Vijayalaxmi, 1975; Vijayalaxmi and Visweswara, 1976; Vijayalaxmi, 1978). According to Tritsch, these studies are the "most convincing and comprehensive group of studies to demonstrate the harmful effects of irradiated food" (letter May 10, 1988, p6). These studies deserve careful consideration since they seem to provide evidence that irradiated food has a biological effect which has been replicated in several animal species, including human children; and the effect appears to be on the genome of peripheral lymphocyte cells, which seems to justify concerns about the delayed genetic effects of consuming irradiated food.

In these studies, the researchers fed freshly irradiated wheat to a number of different animal species (malnourished human children, macaque monkeys, and rats) and measured the occurrence of polyploidy in peripheral lymphocyte cells. Polyploidy is the occurrence of multiples of the normal chromosome complement (46 pairs in humans) in the cells. The authors of these studies assumed that polyploidy was an indirect measure of genetic damage. It needs to be emphasized that this assumption means that data

cited on polyploidy do not bear in any way on the capacity of irradiated food to cause DNA damage.

Bhaskaram and Sadisavan (1975) conducted a study "to determine the effects of feeding irradiated wheat to children suffering from protein-calorie malnutrition" (p130). The subjects were 10 children aged from 2 to 5 years who were suffering from kwashiorkor and showing growth retardation. They were placed on diets of 4g protein/kg and 200 kcal/kg body weight which contained 20g wheat/kg. Five children received wheat which had been irradiated in the previous 3 weeks and another five children received wheat which had not been irradiated. The way in which the children were allocated to these two conditions is unclear; they were reported to be "divided" into two groups. Bhaskaram and Sadisavan later repeated the study in a group of children who were fed on irradiated wheat which had been stored for 12 weeks before being consumed.

Bhaskaram and Sadisavan reported that the children who had been fed freshly irradiated wheat showed an increased rate of polyploid cells in peripheral blood lymphocytes. The increase first became apparent at 4-6 weeks; it increased while the children remained on the diet, and it slowly returned to normal after the irradiated wheat was withdrawn. The group which received irradiated wheat after 12 weeks of storage showed a smaller increase in the rate of polyploidy. The findings did not show any increase in "chromosomal aberrations like breaks, gaps and deletions" (p134). Bhaskaram and Sadisavan argued that their findings "clearly indicate that the appearance of polyploid cells is due to

feeding irradiated wheat" (p134). While acknowledging that the "precise biological significance of polyploidy is not known", they argued that its occurrence was cause for concern since polyploid cells "occur in malignancy, after exposure to radiation, during viral infections, and in senility" (p134). We would add that polyploid cells are also found in normal people.

Vijayalaxmi and Sadasivan (1975) investigated "the effects of consuming irradiated wheat on bone-marrow chromosomes in well-nourished and malnourished rats" (p135). 52 weanling rats were "divided" (randomly?) into two groups, one of which was fed on a low protein diet, and the other of which were fed on a rich protein diet for 8 weeks. After eight weeks, 8 animals in each group were sacrificed to assess the effects of malnourishment on the occurrence of chromosomal breaks and deletions, and polyploid cells in bone-marrow cells. The remaining animals were assigned to one of three conditions for 12 weeks: (i) unirradiated wheat, (ii) freshly irradiated wheat, and (iii) freshly irradiated wheat plus a protein supplement of caesin. The wheat had been irradiated at 75 krad (0.75 kGy) and fed to the animals within 20 days of being irradiated.

The results showed that irradiated food increased the rate of polyploidy in both well and poorly fed animals. Malnourishment had a much larger effect on breaks and deletions than did irradiated food. They interpreted their results as showing that irradiated food caused an increase in polyploidy in peripheral lymphocytes and repeated their previous remarks that it was difficult to suggest a

mechanism for the effect, "the precise significance" of which was "not clear" (p141).

Vijayalaxmi (1975) performed two linked studies in Wistar rats which examined the effects of consuming irradiated wheat on the occurrence of polyploidy and chromosome breaks in bone marrow cells. In the first study, 30 rats were assigned to one of three conditions for 12 weeks: (i) unirradiated wheat, (ii) freshly irradiated wheat, and (iii) stored irradiated wheat. In the second study rats were fed on freshly irradiated wheat and 6 animals were sacrificed at the end of 1,2,3,4,6,8 and 10 weeks in order to see what duration of consumption was required to increase the rate of polyploidy. Neither study showed any effect on the rate at which chromosomal breaks and deletions occurred. The results for polyploidy confirmed the earlier findings: only the animals fed on freshly irradiated food showed an increased rate of polyploidy, and, in the second study, the increase in the rate of polyploidy was not detectable until the animals had been on the diet for 6 weeks.

Vijayalaxmi (1978) carried out a similar study using *Macaca mulatta* monkeys as experimental subjects. 21 monkeys were assigned to receive one of the following diets for 10 months: (i) unirradiated wheat, (ii) freshly irradiated wheat, and (iii) stored irradiated wheat. She measured the occurrence of polyploidy and chromosomal breaks and deletions. There were no differences in the rates of chromosomal breaks and deletions but agian there were differences in the rate of polyploidy: only animals fed on

the freshly irradiated wheat showed an increased rate of polyploidy.

Vijayalaxmi and Visweswara (1976) supported the findings of the studies of polyploidy by conducting a study of the effect of freshly irradiated food on **dominant lethal mutations** in rats. In this study, male Wistar rats were fed on either a good or a poor diet for 8 weeks and then 4 animals from each group were mated with 3 virgin females per week for 4 weeks in order to see what effect a low protein diet had on male reproductive performance. The latter was measured by a "mutagenic index" which was the ratio of dead embryos to total implants. This index was based on the assumption that the occurrence of mutations would produce an increase in the mortality of embryos after implantation in the uterine lining. The remaining animals were fed on either irradiated or nonirradiated wheat for 12 weeks before being mated with 3 virgin females per week for 4 weeks. Vijayalaxmi and Visweswara reported a higher mutagenic index among the offspring of animals which had been fed upon the irradiated wheat.

AN EVALUATION OF THE NIN STUDIES

We need to consider four things in evaluating the safety of the NIN studies: (i) were the experimental designs and statistical analyses adequate? (ii) to what extent have their results been replicated by other researchers? (iii) were the experimental methods, e.g. choice of measures, appropriate? and (iv) how biologically plausible are the results? Answers to the first two questions enable us to decide whether the consumption of irradiated food does or

does not have a reproducible biological effect. Answers to the third and fourth questions enable us to decide whether any such effect is a biologically important one.

(i) Experimental Design and Statistical Analyses

The experimental designs of each of the NIN studies appear to be adequate in that the choice of conditions under which the animals were observed (on diets of irradiated and nonirradiated wheat) provided an opportunity to answer the question: does a diet of irradiated wheat increase the rate of polyploidy? The authors do not clearly state that the animals were **randomly** assigned to receive either freshly irradiated food or not but they may be given the benefit of the doubt since the importance of random assignment to groups is widely understood in experimental science.

The major difficulty in evaluating the quality of the statistical analyses is that they are inadequately reported. In some of the studies (e.g. Bhaskaram and Sadisavan, 1975; Vijayalaxmi, 1975) it is impossible to judge the adequacy of the analyses because the experimenters do not describe the statistical analyses that were conducted. Additionally, in each of these experiments insufficient data are reported for an independent analysis to be performed. The statistical analyses of the other studies (e.g. Vijayalaxmi, 1978; Vijayalaxmi and Visweswara Rao, 1976) seem to be more appropriate. On the whole, the NIN investigators standards of statistical reporting are less than satisfactory but it is arguable that they were no worse than many other studies in the toxicological literature at the time. The consequence of the poor standard of statistical reporting is that we are

not able to make confident judgements about whether their data support their conclusions.

(ii) Replicability of Findings

The most serious concern about the NIN studies has been the mixed outcomes of attempts by other researchers to replicate their results. Several investigators have failed to replicate the NIN results in the same species (Chauhun, Aravindakshan, Kumar, Rao, Aiyay and Sundaran, 1977; Reddi, Reddy, Ebenezer and Naidu, 1977; Tesh, Davidson, Walker, Palmer, Cozens, and Richardson, 1977) while one other investigator has reported similar results in a different species (Renner, 1977).

Replication of findings is the gold-standard of dependable data in science (Fisher, 1949; Tukey, 1986). The consequence of a failure to meet this standard is doubt about the credibility of the research findings. In the case of a single result, a consistent failure to replicate in well-controlled studies suggests that the positive result was due to chance. In the case of a series of studies, as in the NIN case, the failure of independent investigators to replicate suggests the possibility of experimental error or consistent confounding.

Failed Replications

Four groups of investigators have failed to replicate one or more of the NIN studies on polyploidy (George, Chaubey, Sundaram and Gopal-Ayengar, 1976) or dominant lethal assay (Chauhun et al, 1977; Reddi et al, 1977) or both (Tesh, Davidson, Walker, Palmer, Cozens, and Richardson, 1977). One further group whose work is often

cited as a successful replication (Anderson, Clapp, Hodge and Weight, 1981) are also included here for reasons given below.

George et al (1976) conducted a series of three experiments on the frequency of polyploid cells in the bone marrow cells of Wistar rats which had been fed on freshly irradiated wheat. In the first experiment six animals were either fed on freshly irradiated wheat or not. In the second experiment, a more complicated experimental design was used to examine the effect of adding irradiated wheat to diets with varying constituents. In the third experiment a single group of rats was fed irradiated wheat within 24 hours of irradiation and levels of polyploid cells in their bone marrow were compared to those in the control condition in the first experiment. In none of these experiments was there an increased rate of polyploidy in the animals fed on the irradiated wheat. The differences in the rates of polyploidy in each case were very small (0.21 ± 0.05 versus 0.25 ± 0.04 in the first experiment and 0.28 ± 0.03 in the third experiment). With only six animals per group, however, the chances are high that a small difference may have escaped detection.

Chauhun et al (1977) conducted three sequential experiments to examine the effects of feeding freshly irradiated wheat on the dominant lethal assay test in Wistar rats. In the first experiment they examined the acute effects of feeding rats on irradiated wheat (within 24 hours of irradiation) for 7 days. In experiment two they fed rats on irradiated wheat for six weeks and in experiment 3 they

extended this period to 12 weeks. At the end of the feeding period in each experiment, the male rats were mated with three virgin female rats for 7 days, and then with three new females for 5 weeks in experiments 1 and 2, and 8 weeks in experiment 3. The females were killed 11 days after mating and the number of live and dead implanted fetuses were counted. The test (irradiated diet) and control (nonirradiated diet) animals were compared on five measures of reproductive outcome. The only statistically significant differences between the groups in the large number of statistical comparisons that were performed in these experiments favoured the control group (i.e. showed lower rates of adverse outcomes in the control group). There are two reasons why it is unlikely that these failures to replicate are attributable to lack of statistical power: first, more animals were studied, over a longer period of mating; and second, these animals were fed on irradiated wheat within 24 hours of irradiation whereas the NIN animals had been fed on irradiated wheat within 20 days of being irradiated.

Reddi et al (1977) used the dominant lethal assay in male and female mice to assess the cytogenetic effects of irradiated wheat. They conducted separate dominant lethal assays in male and female mice comparing animals which had been fed on one of the following: a control diet; a diet consisting of wheat irradiated at 20 krad; and a diet of wheat that had been irradiated at 200 krad. After being fed on these diets for 180 days, male mice were mated with virgin females. Half of the females were allowed to litter

and the rest were killed at 14 days gestation. The outcomes assessed in those allowed to litter were: litter size, sex ratio, and growth rate. The outcomes assessed in those that were sacrificed were: pre- and post-implantation loss, and total fetal loss. In the study of female dominant lethal assay, all females were sacrificed after 14 days and assessed for pre- and post-implantation and total fetal loss. There was no evidence of differences between the progeny of male mice fed on the three diets on any of the measures of outcome, and no suggestion of dose-response relationships which failed to achieve statistical significance. The same results were observed among the progeny of the female mice.

The study of ***Anderson, Clapp, Hodge and Weight*** (1981) is usually quoted as a successful replication of the NIN study of dominant lethal assay but we believe that this interpretation is mistaken so it is included under failed attempts to replicate.

Anderson et al conducted a series of four studies on the effects of consuming irradiated food on the dominant lethal assay in mice. In these experiments, male mice were fed on three different types of laboratory diet, which had been irradiated or not. In several experiments three doses of irradiation were studied (1, 2.5, and 5 megarads); in another the food had been stored before consumption or not; and in two studies a "positive control" was included, i.e. a group of animals was given a chemical which was a known mutagen (cyclophosphamide) to demonstrate that the experimental system was sensitive to the effects of a known

mutagen. The male mice were fed on the irradiated or nonirradiated diets for 3 weeks and then mated with 3 virgin females for each of eight weeks. The positive controls were fed on nonirradiated food and injected with the cyclophosphamide 2 hours before the first mating. The outcomes measured were the number of implanted fetuses and the number of early fetal deaths at 14 days after mating.

The results clearly showed that the cyclophosphamide produced a decrease in the number of implanted fetuses and an increase in the rate of early deaths during the first three weeks post-injection. This effect was consistently observed in the three experiments which included this positive control. By contrast, there were a small number of statistically significant differences in the groups that were fed on the various irradiated diets (6 out of the 84 or more tests conducted) but these were consistent with the effects of chance. The pattern of differences showed neither consistency across weeks within studies nor between studies (they occurred in weeks 4, 7 and 8 in different studies and there were no consistencies in the different diets). Even more disturbingly, there were no consistent effects of storing the food on either measure: it made no difference at all to the total number of implants per pregnancy, and the only difference in the rate of early deaths showed a lower rate in the freshly irradiated wheat!

The studies of ***Tesh, Davidson, Walker, Palmer, Cozens, and Richardson*** Tesh et al (1977) are the most convincing of the attempted replications of the NIN studies. These studies, which were conducted at the request of the European

Food Irradiation Project, attempted to replicate the results of the NIN studies of polyploidy and dominant lethal assay. Two independent scientific laboratories attempted to replicate the Indian study using Wistar rats as the experimental animals. Sex-matched litter-mates were randomly assigned to one laboratory or the other, and the animals in each laboratory were fed on a diet which came from the same source. These precautions were taken to reduce the possibility of the results being peculiar to a single laboratory.

In the first study of bone marrow polyploidy, the animals in each laboratory were randomly assigned to receive a diet of either nonirradiated wheat, or a diet of irradiated wheat 2, 4, or 8 weeks after being irradiated with 75 krad. Only the results for the animals fed on the freshly irradiated wheat are reported. The other groups were included to examine the possibility of a dose-response relationship if the irradiated wheat had produced an increase in the rate of polyploidy.

In the course of this experiment one of the experimental diets was unaccounted for and there is the possibility that it may have been fed to the control animals. The researchers continued the study but added an additional control group to control for the effects of this possible error in the allocation of irradiated wheat to the controls.

A notable feature of the Tesh et al studies was that the experimenters included a double-blind assessment of the occurrence of polyploidy by two independent observers

(readers 1 and 2). That is, the occurrence of polyploidy in each preparation was independently assessed by two observers who were unaware of which condition the animal had been studied. This precaution was introduced to examine the degree to which different observers were able to agree upon the presence or absence of polyploid cells.

The results failed to show any increase in the rate of bone marrow polyploidy among the animals which had been fed on irradiated wheat. There was no suggestion that an increase in polyploidy went undetected: the mean difference in the rate of polyploidy was very small. The mean rates of ploypoloidy were 0.095% in the control condition and 0.104% in the irradiated condition (these are the weighted means for each condition averaged across both of the readers).

Because the result was negative it is necessary to examine the statistical power of the Tesh et al study in comparison to that of the NIN studies. Detailed power calculations, which are shown in Appendix A, indicate that Tesh et al's study had at least a 96% chance of detecting a difference as large as, or larger than, that detected in the Vijayalaxmi (1978) study (0.04% vs 0.58% rates of polyploidy respectively). In addition, the results in the control group fed non-irradiated wheat which was added after the diet went missing were not statistically significantly different from those of the control group which may have inadvertantly been fed one batch of irradiated wheat.

The study of the inter-observer agreement in the assessment of polyploidy showed there was poor agreement between the two observers on the rate of occurrence of

polyploid cells in the bone marrow. The two readers produced estimates of the incidence of polyploidy which consistently differed by a factor of two or more. This suggests that judgements of polyploidy are susceptible to observer error, which is a substantial fraction of the difference observed between irradiated and unirradiated wheat in the NIN studies. For example, the NIN investigators reported rates of polyploidy 0.58% in the group that consumed irradiated wheat and 0.04% in the control group, while Tesh et al reported a difference in the estimated rate of polyploidy between the two observers of 0.15% and 0.05% respectively. Even the level of agreement about either the presence (52%) or absence (58%) of one or more polyploidy cells was only slight. (Cohen's kappa measure of agreement (Feinstein, 1985, p185) was a very low 0.09). The poor level of agreement on the occurrence of polyploidy demonstrates the necessity for "blind" evaluation of polyploidy in order to eliminate the possibility that the expectations of the observers produced spurious differences between conditions. This precaution was not followed in any of the NIN studies.

The second study of Tesh et al was conducted in parallel with the first. The same animals were also assessed for the "incidence of micro-nucleated polychromatic erythrocytes" in their bone marrow cells. There were no differences between the experimental and control animals, and the average results overall were within the reference range for the laboratory. This negative result is important since this technique is regarded as a much more meaningful

and sensitive test for genotoxins than is the induction of polyploidy.

In the third study Tesh et al attempted to replicate the findings of the Vijayalaxmi and Visweswara Rao (1976) study using the dominant lethal assay. In this study 75 male rats were assigned to one of five conditions: control (unirradiated wheat), a single short exposure to irradiated wheat followed by recovery, and three groups fed on irradiated wheat 2, 4 and 8 weeks after it was irradiated. Each male was mated with 2-3 virgin females for 10 weeks (except for group 1 which was only mated for 6 weeks). Multiple endpoints were assessed, including fertilization index, morula and blastocyte indices, pre-implantation loss, number of corpora lutea, and post-implantation loss. They also examined mortality, food consumption, body weight gain and mating performance.

The results showed some variation between the groups in these outcomes but this was unrelated to exposure to irradiated wheat, nor did the pattern of results resemble that observed by Vijayalxmi and Visweswara Rao (1976). The failure to find any such effects is especially noteworthy for a number of reasons. The effect observed by Vijayalxmi and Visweswara was a large one and Tesh et al used four times as many animals as Vijayalxmi and Visweswara so that the chance of any major effect having gone undetected is small. In addition, Tesh et al measured a great many more indices of reproductive performance, and they studied their animals over a 10 week rather than a 4 week mating period,

thereby increasing their chances of finding an effect, if indeed one existed.

Successful Replications

The only reportedly successful replications of the NIN studies have been studies of polyploidy (Anderson et al, 1981; Renner, 1977). Since the Anderson et al study has been discussed above, only the Renner study will be considered here.

Renner studied the effects of a diet of irradiated wheat on the occurrence of chromosomal breaks and polyploidy in the bone marrow of Chinese hamsters. Animals were randomly assigned to one of three groups: a control diet; a diet of irradiated wheat for 24 hours; and a diet of irradiated wheat for 6 weeks. Renner took care to check the validity of his cytogenetic methods against those of other laboratories and he ensured that readings of polyploidy and chromosomal breaks were made "blind". He also included adequate samples of animals in each condition (25, 26, and 25 respectively). He failed to find any evidence of differences between the three conditions in chromatid gaps or breaks but there were differences in the rates of polyploidy (0.06%, 0.27%, and 0.32% respectively). Renner followed up the significance of the polyploidy in a series of other experiments the details of which are not reported. According to Renner, these subsequent studies suggested that the effect of irradiated wheat on polyploidy showed a dose-response relationship in the range of 1 to 4 Mrads, and disappeared after the wheat had been stored for 6 weeks.

Summary of replicability: Given the conflicting results it seems difficult to make any summary statement about the extent to which the NIN results have stood the test of replicability. The replicability of the dominant lethal assay is the most doubtful. Other researchers have been unable to replicate the result on dominant lethal assay despite using larger groups of animals, which have been mated over longer periods, and which in some cases were fed on even more freshly irradiated wheat than that used by the Indian investigators. The standing of the polyploidy finding is less clear because well-controlled studies have obtained both positive (Renner, 1977) and negative results (Tesh et al, 1977). The latter conflict in findings suggests that, if there is a real effect, it may depend upon some unusual features of experimental design (e.g. the protocol adopted or experimenter inexperience with the normal incidence of polyploid cells, especially in bone marrow).

(iii) Substantive Criticisms of the NIN Studies

Two substantive criticisms have been made of the NIN studies of polyploidy. The first concerns the adequacy of the NIN investigators' experimental technique; the second concerns the specificity of polyploidy as an index of genetic damage.

Evidence on the first matter was given by Dr Ruth Moore, an expert witness in the field of cytogenetics (Hearings, 15th April, 1988). She argued that the technique used by the investigators to fix the peripheral lympocytes for cytogenetic analysis was likely to produce spuriously high estimates of polyploidy, and had for this reason been

abandoned by cytogeneticists. She also argued that the NIN results were vitiated by errors in experimental technique since the rate of polyploidy observed in the group that consumed irradiated food were within the range of subjective error whereas those in the control group were suspiciously low (namely, zero). Other commentators have made the same point (e.g. Brynjolfsson, 1986).

The second objection to polyploidy is more fundamental, namely, that it is a poor indicator of genetic damage, even when it is measured accurately. Dr Moore, for example, argued that polyploidy occurs for a variety of reasons that are unconnected with radiation damage, e.g. as a part of the normal process of cell development in the case of megacaryocytes. She argued that a more appropriate measure of genetic damage was the occurrence of an increase in chromosomal breaks and deletions. ***It is noteworthy that although these structural chromosomal abnormalities were assessed in the NIN studies none of the studies observed any increase in such abnormalities. Nor did any of the attempted replications which also measured breaks and deletions (e.g. Renner, 1977).***

(iii) Biological Implausibility

A major problem with the results of the NIN studies is that their findings are biologically implausible given what is known about the radiolytic products and the processes of normal cell metabolism. The major implausibility is that although irradiation produces chemical changes in food, these chemicals occur in extremely small quantities, have

short half-lives, and occur in much larger quantities in other food and endogenously in body cells.

The major radiolytic products about which opponents of food irradition appear to be most concerned are hydrogen peroxide, superoxide radicals, and oxygen radicals, and some of their reaction products, such as hyderoperoxides. Those who are concerned about these chemicals seem to have overlooked the fact that *all* of these chemicals are present in a wide variety of foods at significantly higher concentrations than those which are produced by food irradiation using the relatively low doses (less than 10 KGy) which are likely to be used in practice.

More importantly, hydrogen peroxide and superoxide are continuously generated within human cells and subcellular organelles (e.g. peroxisomes) as a side-product of cell metabolism. These molecules are, in turn, the major sources of oxygen radicals within the bodies of animals and humans. One of the important bodily defenses against bacterial infection is a high level oxygen radical burst following phagocytosis of certain types of potentially harmful bacteria. The oxygen radicals kill the bacteria but not the human cells, which demonstrably have significant capacity for defense against oxygen radicals.

Because animal metabolism is basically an oxidative process, the generation of the inorganic molecules noted above is an essential feature of life. *All* organisms have accordingly evolved strategies for coping with the potential harm that constant exposure to oxygen radicals may pose. The sorts of interactions between oxidative radicals, for

example, and organic molecules which might be expected to occur in irradiated food are found both in food treated in other ways, and in the cells of living animals. More importantly, many enzymes protect cells from oxidative damage, examples including superoxide dismutase, glutathione peroxidase and the glutathione transferases. Such enzymes have to be present in all organisms which depend on oxygen for their existence in order to deal with oxidative damage, as indeed do enzymes necessary to remove the oxidative damage from DNA which also occurs on a regular basis. Recent evidence suggests that the metabolic rate of different animal species determines (i) the amount of oxidative damage per day which their DNA will receive, and (ii) the amount of oxidative damage which therefore has to be removed daily to avoid harmful long term effects.

The conventional argument that we cannot rely on information obtained in animal experiments to provide information about the effects of irradiated food on man has much less validity than may be anticipated for other types of chemicals. This is so for several reasons already outlined, namely, the universality of oxidative damage, the fact that it is caused by simple inorganic molecules rather than organic man-made chemicals, and the evolution of mechanisms in all cells to protect DNA from internally generated oxygen radicals by constantly monitoring for oxidatively damaged DNA bases and removing them. Given the 24 hour-a-day production of significant amounts of oxygen radicals and other oxidative species within man and other animals, it is extremely implausible that the minute

additional contribution which might be made by consuming irradiated food could significantly alter the course of the natural events in living cells - especially at the genetic level.

For all these reasons, the fact that no reproducible evidence of adverse effects appears to have been found over many years of experimentation is entirely consistent with what is known about the chemical charges which result from food irradiation.

OTHER EVIDENCE OF SAFETY

There is other evidence which is pertinent to the issue of whether the consumption of irradiated food produces genetic effects: the Chinese studies of the effects of feeding human volunteers on irradiated food, and the experience of the Walter and Eliza Hall Institute with mice bred and reared on a wholly and heavily irradiated diet.

Chinese Feeding Studies

The results of the majority of the Chinese studies are unfortunately only reported second hand by Brynjolfsson (1986) who attended a Conference on food irradiation in Shanghai in April 1986. According to Brynjolfsson, the Chinese investigators have conducted a large series of studies in human volunteers in which a wide variety of biological indices, including polyplpoidy. have been measured. In none of these studies has any effect of consuming irradiated food been observed. The most convincing study was one on volunteers who were fed for 13-15 weeks on a diet which consisted of wholly irradiated diet. In all of these studies the incidence of polyploidy was measured; in

no study did it occur at a higher rate among those who were fed on irradiated food.

We have been able to review one of the Shanghai feeding studies which has been published in an English language journal (Shanghai Institute of Radiation Medicine, 1987). In this study 70 volunteer medical students were randomly assigned to receive an irradiated or non-irradiated diet comprising 35 different food stuffs for 90 days. The foodstuffs which were irradiated at doses between less than 1 and 8 KGy, comprised 60% of the volunteers' diet throughout the 90 days of the experiment. The study was conducted under double-blind conditions, i.e. neither the volunteers nor those assessing their health were aware of which diet they were receiving. A wide variety of medical endpoints were measured (e.g. body weight, blood and urine, EKG), including polyploidy, sister chromatid exchanges, and the Ames test for mutagenicity of the subjects' urine collected over a 24 hour period. Two of these measures (blood urea nitrogen and polyploidy) showed significant changes over the period of the study but neither pattern of change was consistent with an effect of consuming irradiated food. The blood urea nitrogen result, for example, arose because the irradiated group mean was below that of the unirradiated group mean *before* the experimental diet was introduced; the means for both groups were not statistically significantly different at the end of the 90 day trial. In the case of polyploidy, *both* groups showed an equal and significant increase in the rate of polyploidy over the course of the study.

Walter and Eliza Hall Institute

Three witnesses from the Walter and Eliza Hall Institute described the Institute's experience with breeding and raising 61 generations of mice which have been fed exclusively on a diet of irradiated food. Although it did not come from the results of a formally designed scientific experiment, their evidence was valuable for the following reasons. First, the researchers had no interest in promoting food irradiation. Second, their animals were fed exclusively on food which was more heavily irradiated than the food which is proposed for human consumption. This is because irradiation is used to *sterilize* the food so that animals are raised which have not been exposed to any micro-organisms that will affect the functioning of their immune systems. Third, because of the high doses and the fact that irradiated food comprises the entire diet of the animals throughout their development, any major genetic effects should be detected, if they occur. Fourth, although a control group of mice was not included, the central focus of research interest at the Walter and Eliza Hall Institute whould allow even small increases in the rates of cancers or birth defects to be detected. The main interest of researchers at the Institute is the functioning of the immune system of their experimental animals and also the occurrence of tumors. Accordingly, the occurrence of unusual rates of either of these effects in their animals would be of particular concern to them, especially if they were occurring at a higher rate than observed among studies emanating from laboratories that used heat sterilzation of

food. Fifth, detailed records have been kept of the fertility of these mice, and of the rates of malformations among animals born in the colony, so that any such effects would also have been detected. Sixth, 61 generations of mice have been reared on this diet, (i.e. several million animals), so that a reasonable opportunity has been provided for the detection of any transmissable genetic defects that may be caused by irradiated food.

Conclusions

The claim that the consumption of irradiated food causes genetic changes has not been substantiated. Nor has a *prima facie* case been presented in its favour.
The strongest evidence in favour of the claim is very weak, the occurrence of polyploidy in bone-marrow or peripheral lymphocytes in organisms fed on freshly irradiated wheat, as reported by the National Institute of Nutrition. There are several reasons to doubt the import of these findings. First, there are doubts about the reliability of the phenomenon, in that other researchers have been unable to replicate the NIN results. Secondly, polyploidy appears to be a poor indicator of genetic damage; it may arise for a variety of reasons which are unconnected with radiation exposure, including poor experimental technique. Third, there are major biological implausibilities in the chain of occurrences which allegedly links the consumption of irradiated food with the occurrence of genetic effects.

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APPENDIX A:

Power Calculations of Tesh et al Study of Polypoidy

Four quantities are required for a power analysis, namely, the size of effect (ES) which is to be detected, the number of subjects studied (N) the type 1 error rate, and the desired power (the probability of detecting a difference if one exists). In the present case, N and the type 1 error rate are fixed and we need to have an estimate of the ES in order to estimate the achieved power. To obtain the ES we need to know the average difference between conditions (irradiated and nonirradiated diets) and an estimate of the variation in this measure.

An estimate of the size of effect to be detected was obtained from the Vijayalaxmi (1975) study. In this study two groups of 10 rats were fed on either freshly irradiated or nonirradiated wheat for 12 weeks before the occurrence of polyploidy was measured in their bone marrow. Vijayalaxmi reported that the difference between these two groups of 0.58% and 0.04% polyploid cells was "statistically significant". They did not report either an estimate of variability in this measure, or the statistical test they used. A conservative estimate of the standard error of the mean can be obtained if we assume that the difference between these means was just statistically significant by a

t-test at $p < 0.05$ as follows:

$$t_{observed}\ (18df) = [(0.58 - 0.04)/\ SE_m] \geqslant t_{0.05}\ (18df)$$

i.e. $SE_m \leqslant 0.025$

(where $t_{observed}$ (18df) is the obtained value of t with 18 df, SE_m is the standard error of the mean, and $t_{0.05}$ (18df) is the critical (95th percentile) value of t with 18df.

Since $SE_m = \sqrt{s^2\ (1/N_1 + 1/N_2)}$ it follows that:

$$s \leqslant 0.58$$

and the standardised difference between means

$$ES \leqslant 0.54/0.58$$

i.e. $\leqslant 0.94$

or approximately 1.0 in round figures.

Since the number of animals observed under each condition was unequal, a weighted mean sample size is used (28 in this case). Referring to Cohen's (1977) power tables (table 2.3.5, p36) reveals that a comparison involving a weighted mean sample size of 28 provides at least a 96% of detecting a ES of 1.0 or greater with a type 1 error rate of 0.05.

APPENDIX 5

BOTULISM RISK

Introduction

There are seven immunologically distinct kinds of Clostridium botulinum, Types A through to G. All can produce lethal toxins under certain circumstances. The spore-forming bacteria are found in soil and water environments and grow best in anaerobic environments. Types A, B, E and F can cause human botulism. Proteolytic A and most B and F strains do not grow below 10°C so that meat or fish spoilage is obvious and protein foods will be rejected on these grounds. Non-proteolytic E and some B and F strains grow at lower temperatures down to about 5°C although type E will grow at lower temperatures (down to 3.3°C) under specialised laboratory conditions. Type E toxin is easily inactivated by heat and botulism does not seem to have been associated with eating cooked fish, although botulism outbreaks have been traced to eating uncooked, smoked, salted, fermented or canned seafood fishery products such as tuna.

The possibility of increased risk of botulism has often been raised as new technologies have been introduced, such as vacuum packaging in the late 40's, cooking liver sausage in Saran film (50's), new thermal process for producing shelf-stable canned hams (60's), reduction or elimination of nitrites from cured meats (70's). In all cases the anticipated problem did not eventuate, (Tompkin, R.B. (1986) Food Technology, 40, 172).

Perceived Problem for Radiation Treatment of Fish

When fish are exposed to low doses of radiation to extend their shelf-life, the radiation sensitive bacteria which normally cause spoilage are considerably reduced in number. The public health concern is that under these conditions the more radiation resistant Type E Clostridium botulinum, if present, would grow faster than the organisms which remain and toxin could be produced before the fish is rejected because of obvious spoilage.

Current Regulatory Status

The FAO/IAEA/WHO Joint Expert Committee on the Wholesomeness of Food Irradiation at its meetings in 1976 and 1980 examined the results of extensive relevant investigations carried out from the 1960's onwards, mainly in the UK and the US. For these investigations different species of fish were deliberately inoculated, generally with large numbers of Cl. botulinum spores, irradiated and stored under different conditions until spoilage and/or toxin was produced. The Committee concluded that lean fish could be safely consumed after irradiation at a dose of up to 2.2 kGy with subsequent storage at a temperature of 3.3°C and cooking.

These conditions are set out in an annex to the WHO Codex Alimentarius Commission's Recommended International Code of Practice for the Operation of Radiation Facilities used in the Treatment of Foods.

Risk Assessment

The question of a potential botulism hazard arising from eating irradiated fish is therefore only relevant if the known safe conditions are intentionally or unintentionally altered. These could be a change in the packaging, for example, modified atmosphere storage, temperature abuse, or the use of higher radiation doses.

Several factors need to be considered:

- frequency of occurrence of the organism in the product;
- growth conditions required to give lethal toxic doses;
- whether, under these same growth conditions, other microbial spoilage will occur with sufficient production of off-odours to ensure rejection of the product on sensory grounds, and
- whether the product will be cooked before it is eaten to ensure inactivation of the toxin.

Incidence of Cl. Botulinum Type E in Fish or Aquatic Environments

Two relatively small surveys, 21 samples in 1951 and 528 samples in about 1970, failed to isolate Type E from muds, cultivated soils, fish intestines and potato washings collected from NSW, Queensland and Tasmania. Dr J Christian, CSIRO Division of Food Research concluded that "it cannot be assumed that Cl. botulinum Type E is absent from the coastal environment of South East Australia... an extensive survey involving a great many samples may be required to demonstrate the presence of Type E organisms on this continent" (Christian, J. IAEA Tech Report Ser 125 (1971) p. 76). Although Type E was suspected, but not confirmed, of causing two cases of botulism traced to Australian canned tuna (Bennett, N, et al, Med. J. Aust. 1, 804 (1968), it has not been implicated in recent cases of infant and animal botulism in NSW or isolated from the urban and rural environments associated with these cases (Murrell, W.G. and Stewart, B.J. Med J Aust 1, 13 (1983).

By contrast, Type E has been isolated from fish or from coastal or pond sediment samples obtained from several northern hemisphere countries, eg Japan, US, USSR, Denmark, UK. The incidence is extremely variable and generally too low to warrant routine sampling. Where contamination does occur, the degree of contamination in fresh fish is also low, certainly less than one spore per gram and possibly less than one spore per 10 gram of fish.

Growth and Toxin Production

Several factors influence these rates of reaction including:

- fish species (higher in some fatty fish);
- contamination level (higher in deliberately contaminated (10+/g) experimental batches);
- storage temperature, with rates increasing as the temperature exceeds about 5°C;
- packaging (generally, but not always, increased with vacuum packaging compared with oxygen-permeable films);
- radiation dose (there is some evidence that Cl. botulinum Type E spores are injured at 3 kGy and do not grow at 10°C (Rowley, D.B. et al. J. Food Sci 48, 1829 (1983); at lower dose of 2 kGy, toxicity occurred before spoilage at 7.8°C for oxygen-permeable haddock fillets inoculated with 104/g spores, but not at a lower inoculum of 100/gram (Eklund, M.W. (1982) Food Technol. 36 (12) 107).

Packaging Atmosphere

Vacuum-packaging and modified atmosphere storage of fish have also been considered as preservative techniques with a potential hazard for botulism. CSIRO food scientists Eyles and Warth have made an assessment of this risk for vacuum-packaged fish (Fd Technol Aust 33, 574 (1981). They looked at the occurrence of Cl. botulinum in fish and fish products, growth and toxin production in vacuum-packaged raw fish, human susceptibility to toxins (minimum lethal dose), destruction of toxins by cooking. They concluded that the risk of botulism is extremely small and stated:

"The consideration is not one of reducing known botulism from fish but one of assuring its continued prevention. As long as vacuum-packed raw fish are handled with the same precautions that apply to other fresh fish, and proper instructions for handling of the product are prominently incorporated into the labelling, the risk of an outbreak appears remote".

Conclusion

A similar rationale and conclusion that the risk of botulism is extremely small can be made for low dose radiation treatment of fish. In comparison with other countries, the natural incidence of Clostridium botulinum Type E in the Australian environment, should it even be present, must be very low as the organism has not yet been isolated from at least 600 samples tested. The growth rate for low concentrations of spores is very slow. Cooking destroys toxin and even in countries with a comparatively high incidence of

Cl. botulinum Type E, no cases of botulism have ever been associated with fish cooked before it is eaten. Prominent labelling should provide warnings against improper storage. The use of shelf-life date stamps and time-temperature monitors during fish distribution could be considered.

Source: Australian Nuclear Science and Technology Organisation

APPENDIX 6

HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON ENVIRONMENT, RECREATION AND THE ARTS

INQUIRY INTO THE USE OF IONISING RADIATION

ADVISERS REPORT ON RADIATION SAFETY

Introduction

Amongst the various concerns expressed about the use of ionising radiation for the sterilization of various products in general, and the irradiation of food in particular, are the risks to the workers at irradiation plants, the hazards to members of the public, and the dangers of environmental contamination.

This report addresses some of these specific concerns. It reviews current safety procedures at the existing Australian plants used for the irradiation of medical supplies, incidents that have happened at such plants, and also some accidents that have happened overseas involving human exposure.

Radiation Safety

The author of this report was also Chairman of a review of Radiation Safety at the Steritech Gamma Irradiation Facility in Dandenong, Victoria. That Review was conducted on behalf of the Victorian Government. The Review concluded that the plant operates in a safe and satisfactory manner and does not present a significant radiological hazard to either plant operators or members of the public. This report was provided to the House of Representatives Committee.

During the course of the House of Representatives Inquiry the opportunity was taken to investigate the operation and safety of the Ansell-Steritech Plant at Wetherill Park, Sydney, and the Johnson and Johnson Plant at Botany also in Sydney.

Following the visit (19/4/88) to the Johnson and Johnson plant the following notes were prepared.

1. The plant is built to AECL JS6500 series design, and came into operation in 1972. It is used only for the sterilisation of Johnson and Johnson's own products (in practice, mainly tampons).

2. The current loading is about 10 petabecquerel (10PBq) of Cobalt-60, i.e. about 25% of design capacity.

3. The cycle time is 22 minutes. The plant runs automatically, there are no operators in attendance outside normal working hours. However, the control panel is duplicated in the entrance guardhouse which is staffed continuously.

4. The principal plant operator has an AECL training certificate and has also successfully completed the NSW Department of Health's Industrial Radiographers Safety Course.

5. The personal dosimeters (film badges) used are from the NSW Department of Health, with a quoted lower limit of 20 millirem (0.2 millisievert). I reviewed the film results for the past 12 months - all results were less than 0.2 millisievert.

6. The company has 4 RATO-F portable radiation monitors. They are calibrated by ANSTO every three months. The three I inspected (one was away for calibration) were all in working order, with up to date calibration certificates.

7. Some radiation measurements were taken around the plant and obtained the following results:

   a) at the product exit:

      0.01 millisievert per hour with the barrier door shut
      0.07 - 0.08 millisievert per hour with the barrier door open

   b) on the shielding wall directly opposite the source:

      0.005 millisievert per hour at waist height
      0.020 millisievert per hour at head height

   c) general levels around the plant: 0.0001 millisievert per hour (i.e. background radiation level).

   These radiation levels are satisfactory. The film badge results noted in (5) above confirm the low dose rate levels to which plant operators are exposed.

8. The required maintenance procedures are carried out on a monthly basis. The various checks are logged automatically on an electronic recording system. The last check prior to my visit was dated 7/4/88 and appeared correct.

9. Particular enquiries were made concerning the fire that occurred inside the radiation cell area on 14/11/82. This event is discussed in the section on incidents.

10. The overall impression was of a well run plant operating significantly below capacity. The Plant Manager and Principal Operator both had a clear understanding of the nature of the plant, potential hazards and safe operating procedures.

11. It was considered that there is negligible radiation risk to plant personnel during normal operation of the plant.

A visit was made to the Ansell-Steritech Gamma Sterilization Plant at Wetherill Park on 18/4/88. The following observations were made after that visit.

1. The plant is built to AECL specification JS 8900 and it was opened in December 1985 as a commercial irradiation service.

2. The plants design capacity is 80 petabecquerel. The current loading is about 25 petabecquerel.

3. The plant irradiates mainly medical supplies. It could be modified to irradiate foodstuffs but materials handling procedures would have to be changed.

4. At present the plant runs on three shifts, at about 98.4% of the possible maximum operating time. There are two dayshift operators, with one operator on each of the afternoon and night shifts. All the plant operators have AECL competency certificates.

5. The Plant Manager is the designated Radiation Safety Officer. He has attended a radiation safety training course at the Australian School of Nuclear Technology (Lucas Heights).

6. The control panel is interlocked to the Chubb Watching Service. There is a 'deadman' button for single operator control (i.e. an alarm sounds each hour, the operator has to press a button to switch it off - if it is not switched off, Chubb notify the Plant Manager).

7. The Company has three RATO-F portable radiation monitors. They are calibrated at ANSTO. They were in working order and their calibration records were up to date.

8. The personal dosimeters (film badges) used are supplied by the Australian Radiation Laboratory. The reported lower limit is 0.01 millisievert per issue period (usually one month). I reviewed the records for the 8 plant staff who receive dosimeters. During the past 12 months there had only been one recorded dose. That was for 0.01 millisievert. That was not a significant dose.

9. At the request of the local Council a continuously reading ozone monitor has been installed in the plant exhaust system. It alarms at 1 part in 10^7 which is the threshold limit for ozone exposure. The monitor is interlocked with the access door.

10. The plant incident log book was reviewed in some detail. In a typical week (25/3 - 31/3/88) there were 13 entries into the cell. Nine were related to product trials. Of the other 4, 2 were because the cylinder that moves the product failed to contact the limit switch. In such a case the source automatically descends to the bottom of the pool. One was

because the product conveyor missed a carrier due to mechanical touch failure. One was because the source did not come up out of the pool. This was due to a solenoid failure, requiring the solenoid to be dismantled and cleaned. None of the events had any radiological significance and did not involve the operators in any radiation exposure.

Criticisms of Plant Operation

A detailed criticism of the operation of the Ansell Steritech Wetherill Park plant was tendered on behalf of Friends of the Earth by Mr Bob Tait who has a Bachelor of Engineering degree (pp 00127-00129). The plant was reviewed with Mr Tait's criticisms in mind and the following observations on Mr Tait's specific points were prepared.

a) TAIT: There is no power back-up for the plant - a power failure allows the source to return under the force of gravity.

RESPONSE: Even with power available the source descends into the pool under gravity, the rate of descent being determined by the rate at which the air is allowed to exhaust from the pneumatic hoist. The usual time taken is about 25 seconds.

The arrangement is considered to be quite satisfactory as gravity is not a force that can be switched off. Cables can jam with or without a power back-up. Such a back-up would have little, if any, effect on the way such a situation would be handled. If power failed remedial action could not be taken until lighting in the plant room was available. It would be a financial liability to the company, not a radiological hazard.

The Committee may consider that emergency lights be installed in irradiation plants as a general safety measure to enable evacuation in the event of a power failure.

b) TAIT: Small holes have been drilled through the roof to allow restricted manipulations with long handled tools. There is no remote controlled system or equipment to deal with an unshielded source.

RESPONSE: The source is intended to be unshielded during normal operations. If it becomes jammed and if the long handled tools can't manipulate the source back into the pool there would be time to arrange a robot with TV and/or remote arm to manipulate the source within the cell. There would not be any radiological risk to personnel whilst this was being arranged and carried out.

On two occasions the source jammed at the Dandenong plant; each time it was returned to the pool following manipulation of the hoist cable (see section of this report commenting on accidents and incidents).

c) TAIT: There are ineffectual safety arrangements for personnel.

RESPONSE: The arrangement of a geiger counter attached to a key which is used to switch the source control on and off has been misunderstood by Mr Tait. The geiger counter is attached to the key to ensure that people entering the radiation room after the source has been lowered into the pool have a counter with them as part of the entry procedure. It is a back-up check to the installed entrance maze monitor which in turn is interlocked to the entrance door. The key and counter being taken into the irradiation area is also part of the control procedure to prevent the source being raised whilst someone is in the irradiation area but there is also a cable running around the irradiation chamber, which if pulled, switches off the plant.

The chain across the maze is the fourth safety control. (It was actually introduced by Ansell at their Dandenong plant and subsequently adopted by the Canadians). The power supply has to be inactivated to allow the access door to open, the chain supplements this. There would be no reason for anyone to step over the chain.

There is room for improvement in safety training. The Plant Manager has attended a suitable course and the operators have appropriate training from the Canadian representatives when new sources are being installed. This training however relates to plant operation, and the automatic running of the plant. The plant controls are linked with the Chubb Watching Service who monitor the plant operation and require the 'Deadman' switch to be operated every hour.

It is perfectly satisfactory for the action to be 'Ring the Plant Manager' as he (or she) is the appropriate responsible person.

Mr Tait notes that the system is OK only if nothing goes wrong. It should be noted that there are several redundant safety features and the design of the plant is such that even if something does go wrong there is no immediate radiological hazard to plant personnel.

d) TAIT: The ventilation system pollutes the environment.

RESPONSE: At the insistance of the local Council a continuously reading ozone monitor has been placed in the exhaust stack. It is set to alarm at 1 part in 10^7 of ozone. This is the threshold limit value. The alarm is interlocked with the source and if it triggers the source returns to the pool.

The question of mutated bacteria and viruses has been discussed by the Committee and Dr MacPhee has provided advice.

e) TAIT: There are difficulties in achieving an even dose.

RESPONSE: This would obviously be a matter for the relevant Licencing Authority to approve or not approve food irradiation based on any modifications to the plant. The Committee will need to consider recommending appropriate tolerances on doses given. This point is discussed in more detail in the section on dose uniformity.

f) TAIT: 'Spent' Cobalt-60 is a problem.

RESPONSE: 'Spent' in this sense means that a pencil is too low in radiation output to be useful for sterilisation purposes. It is agreed that it is an extremely hazardous source of radiation and will need as much care in transportation back to Canada as do fresh sources.

g) TAIT: Cobalt-60 cannot be "recharged".

RESPONSE: This is incorrect. During the initial manufacture less than 25 % of the initial Cobalt-59 is changed to Cobalt-60, so there is the opportunity to reactivate the sources. Even so they will eventually become a waste disposal problem. Clearly Australia has an international responsibility to ensure that they are stored and disposed of in a safe manner when no longer in use. This would be a matter to take up with the suppliers and the supervising and licensing authority.

h) TAIT: The economic life of the rods is 20 years, whereas the warranty is for 15 years.

RESPONSE: All this means is that the rods will have to be decanted from the source holder and inspected very carefully for signs of corrosion towards the end of the 15 year warranty period. If they are satisfactory, they can be used for another 5 years or so. This is I would suggest, a case of the supplier being appropriately cautious. The pencils are wipe tested every time fresh sources are loaded which is also a check of the containment.

Uniformity of Radiation Fields

Several witnesses (including R. Tait, see e) above) have expressed concern about difficulties that can be experienced in obtaining uniform dose fields and therefore uniform irradiation of any product. The procedures for both calculating and measuring dose patterns has been well developed and at the existing Australian gamma sterilization plants they are as follows:

1. The Cobalt-60 rods are supplied by Atomic Energy of Canada Limited (AECL). That organisation is able to determine the specific activity of each rod produced by knowing a combination of:

   a) The neutron flux in the part of the reactor used for the activation of the Cobalt-59, and

   b) The length of time the rods spent in that neutron flux.

   Other important parameters such as the neutron capture cross-section for Cobalt-59 are known physical quantities.

2. Before any fresh rods are inserted into the irradiator source racks at the operating company's premises, AECL calculate the required position of each (OLD & NEW) rod in the source holding module.
   This is a straightforward computational exercise and is done for two reasons:

   a) To produce a uniform dose field and to determine the strength of that field, and

   b) To obtain maximum useful radiation from the older Cobalt rods.

   Thus the loading of fresh sources can involve a significant re-arrangement of the existing rods.

3. AECL provides the operating company with a list of conveyor timer settings needed to achieve particular doses (for sterilization, 25 kilogray). The timer setting will vary depending on the density of the product being irradiated and to allow for the gradual decay of the Cobalt-60.
   The production of timer settings lists is a non-too-complex mathematical exercise carried out by AECL computational staff who have a wealth of experience in preparing such data.

4. For sterilization procedures doses a little above a certain minimum do not pose problems (except to the operations in terms of 'lost' radiation energy and time). Plant operation therefore can be relatively uncomplicated.

5. For food irradiation:

   a) If doses less than one kilogray are required then, either significantly smaller sources and/or faster conveyor operation are necessary.

   There are no inherent problems in achieving uniform, known and controlled radiation doses.

   b) For doses between one and ten kilogray the same reasoning applies except that obviously larger sources or longer irradiation times can be used.

6. However it should be noted that irradiation of foods requiring the delivery of doses within prescribed limits will require changes to plant operating procedures to ensure correct irradiation.

   If a certain foodstuff of a particular density is to be given a specific dose the conveyor timer will need to be set at a pre-calculated point. This will need to be reset before another food item of a different density, requiring a different exposure level, can be irradiated. This would require the run-out of the first item, irradiation would have to take place on a batch by batch basis, which would slow down the operation of the Plant.

7. In summary:

   a) There are no major difficulties in producing uniform radiation fields of carefully known dose rates.

   b) The half-life of Cobalt-60 is known very accurately and it is a simple mathematical exercise to make allowance for this when calculating irradiation times.

   c) Changes to operational procedures will be necessary if and when food is being irradiated. This should not present any problems as operators already have to change timer settings when materials of differing densities are being gamma sterilized.

Incidents and Accidents

There have been two events at Australian gamma irradiation plants which have been brought to the Committee's attention as evidence of the unsafe nature of such plants.

As part of my work for the Committee I investigated both events in some detail.

An Ansell source jam, which was described by the Company as an 'unusual occurrence' took place at the Dandenong plant (then operated by Tasman Vaccine, a Division of ICI Australia) on 13 August 1980, and an earlier similar event happened in May 1979. The then Production Manager was Mr George West, currently Divisional Manager for the plants present operators, Ansell Steritech. Following a review of the plant and discussion with Mr West I made the following notes:

1. Prior to 1975 cardboard tote (irradiation) boxes were used. These became brittle on repeated irradiation and were awkward to unload. In 1975 Tasman-Vaccine designed a metal frame basket to replace the cardboard boxes. The design worked well until May 1979.

2. In that month a basket gate jammed in the overhead rollers, buckling the gate and jamming the source rack. By repeated manouvering of the source hoist cable and the basket pushers the gate was freed and the source descended into the pool. It took about 30 minutes to free the source.

3. The plant was shut down for a further 8 hours whilst various modifications were carried out, including redesign of the basket gate.

4. At 10.40 pm on August 13 the night shift operator telephoned Mr West with the advice that the plant had shut down but that the source had not returned to the bottom of the pool.

5. On Mr West's arrival at the plant several manoeuvres were tried to move the source rack, including raising and lowering the cable (there was about 6 - 7 inches of movement) using a manual winch which had been clamped onto the cable. This was done in the source hoist room above the irradiation chamber. At about 4.00 am the cable snapped, as a result of friction, and disappeared into the cell. It was not realised at the time that the source had now dropped to the bottom of the pool. The snapping of the cable had given the source rack sufficient momentum to clear the obstruction.

6. On Thursday 14 August at 5.00 am advice was sought from AECL who proposed that they send out an appropriately experienced Engineer and Physicist.

7. At 7.00 am further advice was sought from Canada regarding a possible further option to free the jammed source by slackening the guide cables. AECL advised against this proposal and notified Tasman-Vaccine that a 2 man team had already been arranged and would be in Melbourne by Sunday August 17.

8. Late on Thursday, radiation measurements, by amongst others the State Radiation Safety Section, made it clear that the source was now in the 'safe' position at the bottom of the pool. The cell was entered using standard entry procedures. The source rack was at the bottom of the pool, 17 pencils having spilled out of Module No. 4.

9. The Canadians were advised of the changed situation and arranged instead to send out an installation engineer (Mr Jaeger who now works at Dandenong). He arrived on Sunday 16 August, i.e. within 3 days of the initial source jam.

10. All the cobalt pencils were removed from the rack, inspected and leak tested. The source modules were rebuilt, a new cable fitted and basket modified (again). They have now been replaced by AECL designed standard aluminium tote boxes.

11. The jamming was caused when a basket gate that had become buckled, after falling between two conveyor rollers, caught the tip of the source rack when one of the pushers triggered a shut down.

Comments

a) The incident was caused by a combination of faulty basket/gate design and poor plant maintenance, i.e. sticking conveyor rollers. This latter point is clearly acknowledged in the Company's report and one of the remedial actions taken was to adhere strictly to the preventative maintenance schedules. (Note: My recent inspection of the two Ansell Steritech plants confirmed that maintenance schedules are up to date)

b) At no stage was there any radiological hazard to personnel, either on the plant or to members of the public. This would have remained the case irrespective of how long the shut down occurred.

c) The plant was shut down for 126 hours.

d) The severing of the hoist cable which led to the source dropping to the bottom of the pool was fortuitous and not by design (Note: Mr West's evidence to the Inquiry inferred that the cable was cut deliberately - see transcript last paragraph P 00388 - West"...Eventually we cut the cable and it just went straight down to the bottom of the pool". Mr West continues. "That problem no longer occurs as we now have a source sleeve so that it can be lowered to the bottom of the pool without being impeded", which is correct). The severing of the source hoist cable did, by chance, have the desired effect but this was not realised for some 12 hours.

e) If the snapping of the cable had not released the source the jammed gate would almost certainly have had to be released by remote manipulation from the hoist room using the access holes. How easy this would have been, how long it would have taken, and what radiation exposure the Canadian operators may have received is now impossible to judge.

f) The remedial actions taken, including a source rack sleeve, improved maintenance, and use of a different design of tote box, are such that a repeat of this type of incident is now exceedingly unlikely.

Johnson & Johnson Fire

1. The fire occurred some time during the night of 13/14 November 1982 (i.e. Saturday). It was signalled to the Alexandria Fire Station at 4.36 am Sunday, November 14.

2. The plant was operating normally at 2.00 pm on Saturday, November 13, when the plant crew left. Routine inspections by Security Officers noted "source up" lights indicating that the plant was operating normally at 4.30 pm, 7.10 pm and 9.00 pm on Saturday.

3. At 4.30 am on Sunday 14 November, a Security Officer, on routine patrol heard the fire hydrant pumps operating, he noted that the "source down" light was not flashing. The officer tried resetting the pump, on failing to do so he contacted the duty electrician who noted that the "source down" light was now flashing.

4. The Irradiation Operator was called at 4.40 am. He determined from the control console display that the source was in the pool. The Fire Brigade had arrived but had observed the "entry prohibited" signs and awaited further advice.

5. The Irradiation Operator entered the cell maze using standard procedures but was driven back by smoke.

6. The Chief Radiation Officer of the Health Commission arrived at 5.50 am. He and the Irradiation Operator donned breathing apparatus, entered the maze and determined that there was not a radiation hazard. The Fire Officer directed that the sprinklers be switched off so that the internal condition of the cell could be viewed. This was about 4 hours after the initial alarm.

7. The reconstructed sequence of events leading to the fire appears to have been as follows:

   the initial cause appeared to have been the use of poor quality tape used to tape the cardboard product boxes. The tape came unstuck on one of the boxes being irradiated. The lid popped up and on one of the passes the box jammed before the exit maze;

   an associated cause was due to a 115V relay having been plugged into a 12V shutdown circuit. This relay (K52) did not de-energise when the product line stopped. If it had done so the source would have descended into the pool;

   the source was up for about 14 hours irradiating stationary cardboard boxes. One eventually caught fire from the radiant heat emitted by the Cobalt-60;

   the fire activated a thermal detector (there is no smoke detector) and the sprinkler system came on automatically. This in turn de-energised another relay circuit, the plant shut down and the source descended into the pool.

8. At no stage was there a radiation hazard. All personnel involved, both from the plant, the Fire Brigade and the Health Commission followed the correct operational procedures.

9. Several alterations to both plant operations and maintenance procedures were instituted to prevent a re-occurrence. These include:

   colour coding of the control relays. 115V relays are colour-coded RED, and a visual inspection of the relays is made each month;

   the thermal detector has been repositioned;

   an additional sprinkler head has been fitted directly above the source rack to cool the source;

   the control circuitry has been modified so that in the event of a product box jam and a false electrical safety situation then the Unit will shut down after completing a further cycle (i.e. after 22 minutes on the present cycle time).

Conclusions

The fire did not present a radiation hazard to any personnel at any stage.

The personnel from the various groups involved carried out their procedures in a correct manner.

The modifications made should prevent the reoccurrence of a similar type of fire.

In neither incident was there a risk of radiation exposure of either plant or emergency personnel and in both cases the remedial actions taken should prevent a reoccurrence of similar incidents.

Overseas Acccidents

The literature on radiation accidents is not very extensive and the only complete report that has been obtained is of an accident that occurred in Norway in 1982. This led to the death of a technician following uncontrolled entry into the irradiation cell.

The accident happened at the Institute for Energy Technology, Kjeller in a 2.4PBq Cobalt-60 plant. (The Dandenong plant for example, contains 37PBq).

Extracts from the Norwegian report read as follows:

"September 2. 0338. Operational alarm went off due to failure of the conveyor system. The duty operator decided to wait until working hours to institute remedial action.

0707-0712. The service technician arrived. At 0719 he switched off the operational alarm which was registered in the Institute reception room. The reception officer phoned the irradiation plant and after a short waiting period received an 'everything's alright' message from the service technician.

0730. The service technician was found sitting on the steps of the plant building clearly ill. He was taken to the reception centre. It was assumed he had had a heart attack and was taken by air ambulance to hospital.

0800. The research leader and operator arrived. They were aware that the service technician had been sent to hospital.

The research leader noted that the source indicator was green indicating that the source was shielded and that the door to the irradiation room was wide open. He proceeded to check the radiation levels inside the door, found them high and concluded that the technician had been highly irradiated.

By 0840 the emergency team had assembled and prepared the following report on the status of the plant:

> 'dose recorder: irradiation continuously on since 2130 the previous day;
>
> source condition indicator: level 04 the whole source above floor level,
>
> radiation monitors in working order.'

The patients film badge was too black to read after processing. What had happened was that a microswitch had failed giving a source shielded signal and releasing the barring of the door lock even though the positional display showed the source in an elevated position.

Comparison of the two signals would have shown the discrepancy. There was not, however, a positive failure signal.

In addition the radiation monitor in the interlock system had been taken out of service for maintenance and the radiation dose/interlock system was out of action.

Thirdly, the technician failed to use a monitor to check the radiation level before entering the irradiation room.

As Liev Bertig, Director of the Norwegian Institute for Radiation Hygiene put in his report - 'The technician arrives at the plant. The alarm is on and the display at the staircase entrance shows green, source shielded. He fetches

his operational key and enters the control room where also the green light - source shielded-springs into the eye. He turns off the alarm and unlocks the door with the prescribed use of controls. It is important to get the plant moving so why bother with monitors. After all, the safety system is failsafe, even 'idiot-proof'.

And that's it!.

Of course such a system should be beyond human error, but even it can never be made completely proof against malevolent intentions.

Because of the different interlocking system and procedures, probably the simplest of which is fixing a radiation monitor to the control key, the review panel was convinced that the Norwegian accident could not happen at Dandenong. That is why when we considered the maximum credible accident we opted for the emergence of a pencil from the irradiation area.

Going into the control room with the source exposed would kill the person who did it; a pencil coming out of the product maze could kill 3 or 4 plant operators and produce unacceptable radiation levels in areas around the plant. Even if far from lethal they would cause much public alarm and concern.

More recently a radioactivity release has occurred at an irradiation facility in the United States. An extract from the preliminary report reads as follows:

The State of Georgia advised Region 11 on June 7 1988, of a leaking WESF Caesium-137 source at Radiation Sterilizer, Inc., (RSI), an agreement State licensee located in Decatur, Georgia. RSI irradiates medical products and empty food containers but not food products.

The RSI facility is made up of 252 Caesium-137 WESF capsules, each containing anywhere from 43,000 to 50,000 curies of Caesium-137 in 1 25-foot deep pool. The WESF capsules are leased to RSI from Westinghouse Electric Corporation. RSI is licensed to possess a total of 12.3 million curies of Caesium-137.

Preliminary investigations indicate that one or more of the WESF source capsules has been determined to be leaking and has been doing so since some time after June 3 1988.

All safety systems at the RSI facility functioned as designed. Concentration levels in the pool have been measured at .04 microcurie per millilitre, which equates to approximately four curies of Caesium-137. Radiation levels six inches from the surface of the pool measure 12 to 17 millirem per hour.

Ten RSI employees have worked in the operations area since June 3, and some clothing and minor skin contaminations has been measured on several of these employees. Blood work analyses are being conducted on all potentially affected persons.

RSI has closed the facility and has taken action to minimize the work force to only those personnel necessary for recovery operations and to minimize personnel traffic in the operations area.

This incident would confirm the need to recommend against the use of caesium as an irradiation source.

Review of Safety Features

In presenting evidence to the Committee I commented upon the various safety features at Australian irradiation plants. Dr D.D. Mathews, Radiation Safety officer at Flinders University and a member of the South Australian Radiation Advisory Council reflected adversely upon my evidence.

Effectively Dr Mathews made two points:

1. all the described features are prone to human facility,
2. the frequency of shut-down could lead to operator complacency and over-riding of the automatic shut-down.

To take these points further:

1. In discussing the proneness to human error Dr Mathews draws lessons from Three Mile island (TMI) and Chernobyl in that the weakest link in all systems is the operator. In drawing this lesson I suggest that Dr Mathews is only partially correct. What has been shown by reactor accidents (and I would include a larger list than Dr Mathews e.g. Windscale, Browns Ferry, SL-I etc) is that operator error can show up fundamental design flaws. For instance at TMI the operators were overloaded with information, ringing alarms and a vital warning light was obscured by a maintenance workers service tag. At Chernobyl all the operating procedures were deliberately over-ridden in an almost incredible way and the unsuspected positive reactivity of that design of reactor led to the explosion.

   What such incidents have shown (and it is important to include non-nuclear disasters such as Flixborough, Seveso, Bhopal etc) is that, apart from the sound basic design of the plant (and irradiation plants around the world have demonstrated the correctness of the design and building procedures) what is required is:

a) simplicity and redundancy in safety equipment and controls, along with regular checking and servicing;

b) thorough operating training and supervision;

c) an effective independent supervisory authority to ensure that a) and b) are being complied with. This requires legislative controls be both implemented and policed.

These three criteria are, I consider, satisfied in the case of all three existing commercial irradiation plants. They should form part of any recommendations that might be made if food irradiation is approved.

2. By being disturbed about the frequency of shut-downs Dr Mathews shows a lack of understanding of irradiation plants.

On shut-down the source is automatically returned to the shielded position at the bottom of the pool.

Nothing is achieved by the operators over-riding the automatic shut down circuit on the pretence that it isn't working. It shuts down because it is working. The control panel indicates what part of the system had caused the shut-down. The shut-down occurs for a variety of relatively minor reasons which have nothing to do with radiation safety but with the mechanical operation of the plant and the need to obtain correct dosage to the materials being irradiated.

Radiation Dose Limits

Several witnesses have suggested to the Committee that working in irradiation plants presents an unacceptably high health risk. This argument is based on two interlocking premises.

i) any exposure to radiation is harmful,

ii) existing exposure limits have been set too high.

1) Radiation protection practices are based on the understanding that any radiation exposure carries with it some risk. That risk has been quantified within certain broad limits, and the aim is to contain the risks within acceptable limits. What is and what is not an acceptable risk can be argued, Some such arguments have been put forward by Mr Tony Webb who is co-author of 'Food Irradiation - who wants it?' and co-ordinator of various groups concerned with the health of radiation workers, and victims of nuclear weapons tests, radiation accidents etc.

2) Mr Webb's main thesis is that radiation levels, as set by the International Commission on Radiological Protection, and adopted by the appropriate National or State Authorities have been set too high. He argues for a 15 fold reduction in dose limits.

3) Without arguing the merits of Mr Webb's case it is not directly relevant to the question of food irradiation, as the dose to workers can be controlled to as low a limit as may be required.

4) The reasons for stating this are:

a) the recorded radiation doses received at Ansell Steritech in Dandenong have never exceeded 400uSv in any one year (i.e. 0.8% of the current dose limit) and these doses were received during source loading operations, not during routine operations. (Note the lower limit of dose recorded by the dosimeters used is 10uSv per month).

b) the only recorded dose at Ansell Steritech Sydney during the past 12 months was 10uSv received by the Plant Manager. The different source loading system used in the AECL 8900 plant (Sydney) reduces substantially the length of time any worker is near the transport flask during loading operations, thus effectively removing the source of exposure.

c) doses received by personnel at Johnson & Johnson, Sydney were all below the limit of detection of the film badges used by that Company (NSW Health Dept. lower limit quoted as 20 mrem/month=200uSv/month).

d) the monitored radiation levels around the plants are, with the exception of some known positions, all about background. The positions of slightly higher than background radiation levels are such that workers would not be in those positions for any length of time, and in the case of the Ansell Steritech Dandenong Plant are fenced off.

e) levels at the perimeter of the plant are indistinguishable from background whether the source is in the exposed position or in the pool.

Another opponent of food irradiation was Dr J Coulter (now Senator Coulter, Australian Democrats) who also argued that irradiation plants present an unacceptable radiation hazard to workers in the plant.

Dr Coulter argued that by adopting South Australian Health Commission guidelines for investigating radiation doses, and current dose limits, the cancer risk to women receiving such radiation doses could be increased by as much as 19%.

Clearly if this is correct it is an unacceptable risk and presents a very strong argument against the use of large radiation sources (it is in fact an even stronger argument against the medical uses of radiation sources such as diagnostic Xray units, but Dr Coulter didn't persue that point).

Dr Coulter based his argument on several pieces of data as follows:

a) the South Australian Health Commission reviews film badge results every 3 months, and a dose at or about the quarter dose limit would be a trigger for investigation (note: Mrs J Fitch in presenting evidence on behalf of the Australian Radiation Protection Society confirmed this information, she is, by chance, Head of the Radiation Safety Section of the South Australian Health Commission).

b) the current dose limit for radiation workers is 50 millisievert per year (mSv/y), thus the S.A. trigger dose is 12.5mSv.

c) the Biological Effects of Ionising Radiation Third Report (BEIR III) gives a risk estimate of between 344 and 1306 cases of cancer produced per million women per 10mSv of radiation.

To take these data a little further, let us use the upper risk quoted by Dr Coulter, i.e. 1306 cases per million women each given 10mSv.

i.e. $1306/10^6/10\text{mSv} = 1.3 \times 10^{-3}$ per 10mSv
$= 1.3 \times 10^{-4}$ per mSv.

If an action or trigger level of 25% of the annual dose limit is used the dose received would be 12.5mSv.

Thus the upper risk to a woman receiving this dose would be $12.5 \times 1.3 \times 10^{-4} = 1.6 \times 10^{-3}$
$= 0.0016$.

The incidence of cancer in Australia is between 0.25 and 0.33 (i.e. between a quarter and a third of all Australians develop some form of cancer of whom about half die from that cancer).

If the lower figure of 0.25 is taken the additional risk from the exposure to radiation would be 0.0016 giving a total risk of:

$$0.2516$$

Thus the percentage increased risk is

$$\frac{0.0016}{0.25} \times 100 = \underline{0.64\%}$$

(Note: <u>if</u> the BEIR figures are correct, <u>and</u> this average dose was received over a 40 year working life the lifetime risk would be increased by 25%, not 19% as Dr Coulter calculated).

This is the risk to an individual, based on conservative upper risk estimates, <u>before action is taken to reduce such doses.</u>

If the trigger level was set at 25% of the monthly derived dose limit (*), the upper risk estimate would be 0.05%.

Dr Coulter's figures are not applicable to the gamma sterilization plants operating in Australia:

a) no doses have exceeded 0.8% of the annual dose limit (which using the BEIR upper estimate for males would give a cancer risk of 0.00006, i.e. an increased risk of 0.012%),

b) to date all workers in such plants have been males, although this could of course change.

Conclusion

Dr Coulter's arguments, as with those of Mr Webb, whether valid or not, are not relevant to discussions about radiation risks to plant operators working in the types of plants currently in operation in Australia.

The Committee can ensure that this situation continues by making appropriate recommendations about:

a) plant design, especially limits on dose rates;
b) personnel monitoring;
c) trigger levels for investigation of film badge results.

(*) The dose limit is based on an annual figure, 50mSv per year. For convenience, derived limits are used, i.e. 1mSV per week, or 4mSv per month. These figures are not included in legislation, but are used as working limits in practical situations. The figure of 4mSv per month corresponds to the normal film badge issue period.

Possible Dose Limit Revisions

One of the principal sources of information on the effects of irradiation are the victims of the atomic bombs dropped on Nagasaki and Hiroshima. The body that makes recommendations on radiation exposure limits is the International Commission on Radiological Protection (ICRP) and its reviews, inter alia, date from the Japanese bombings.

A meeting of the ICRP was held in September 1987. In a post meeting statement the Commission advised that it is presently revising its basic recommendations (ICRP 26, 1977) and anticipates that the revisions will be completed in 1990.

As part of these revisions the Commission regularly examines papers relating to risk and particularly notes a very recently published technical report by the Radiation Effects Research Foundation entitled 'The effects of changes in dosimetry on cancer mortality risk estimates in the atomic bomb survivors'.

This report was recognised as giving a definitive account of the average changes in organ dose estimates from exposure to the atomic bombs in Hiroshima and Nagasaki, and of the resultant increase in estimated risks of cancer induction. Under the new 'DS86' dosimetry this increase in risk is reported as being by a factor of about 1.4 compared with the risks that would have been estimated by the former 'T65D' dosimetry, assuming a reasonable relative biological effectiveness of such neutron exposure as is likely to have occurred in the two cities.

In addition, although not strictly an effect of the new dosimetry, the longer follow-up (to 1985) of the population sample for whom 'DS86' doses are available so far, makes possible a more reliable estimate than previously of a group who were young (less than 10 years) at the time of exposure. This inclusion and other factors cited in the paper raise the risk estimate for the exposed population by a total factor of the order of 2. This change is for a population of all ages, whereas for a worker population of ages 18-65 the change will be smaller. This information alone is therefore not considered sufficient to warrant a change in the dose limits for occupational exposure.

For the general population, the increase in risk indicated by the new data is also not considered to require change in recommended dose limits, following the reduction (in 1985) in the principal limit from 5 to 1 mSv in a year (from sources other than medical and natural background radiation).

Since the risk data are as yet far from conclusive, the Commission will await the result of the comprehensive evaluations of its sources of epidemiological information that are currently being made, before judging the consequences for the revision of its system of dose limitation.

At a meeting of the International Radiation Protection Association held in Sydney in April 1988, the Chairperson of ICRP, Dr D. Beninson noted that the implementation of ALARA kept most exposure doses to small fractions of the dose limit and an urgent downward revision is not necessary. The ALARA concept is that all doses should be kept <u>As Low As Reasonably Achievable</u> and if correctly executed should ensure that radiation workers receive relatively small radiation doses.

Nevertheless the UK National Radiological Protection Board has as 'an interim measure' recommended that the occupational dose limit be reduced from 50 to 15 mSv per year. It further recommends that the public dose limit be reduced to 0.5 mSv per year from any one site.

Any reduction that may occur in existing dose limits would not affect the operation of those irradiation plants currently operating in Australia. The exposure levels are either zero or very small fractions of the present dose limits.

Future plants, if approved should be able to operate with at least the same degree of radiological control.

Induced Radioactivity

One argument advanced before the Committee by some opponents of food irradiation is that the irradiation process could make the foodstuffs themselves radiation active from induced radioactivity (NOTE: all foodstuffs are already slightly radioactive from naturally occurring radioactive materials such as the decay products of uranium, potassium-40 etc).

It is accepted by scientists working in this field that induced radioactivity does not occur, indeed most opponents of food irradiation accept this fact, including such activists as Mr Webb.

However one paper by a Mr Heiman Julius set out to show that the effects observed in the Indian irradiated wheat study were due to a form of induced radioactivity from what are known as metastable isomers.

The point that Julius set out to prove was:

> the production of polyploidal cells in Indian children fed irradiated wheat came from the irradiation they received as a result of absorbing radioactive materials induced in the wheat when it was sterilized by gamma irradiation.

The basis of his argument was that:

> past studies have shown that polyploids can be produced in human cells by irradiation. Therefore the polyploids in the Indian children came from the irradiation of their cells. He considers that the only source of that irradiation is from residual radioactive materials produced in the wheat and subsequently absorbed by the children. Therefore this proves that sterilization by cobalt gamma rays produces residual radioactivity. The sensitivity of human cells to polyploid production is a much more sensitive indicator than any other form of monitor which is why the residual radioactivity has not been previously detected. The residual activity is in the form of metastable isomers which have (until now) been overlooked. His argument failed to cover several points.

1. He did not consider other possible mechanisms for polyploid production.

2. He did not make any estimate of the amount of induced radioactivity necessary to produce effects. From data he quotes the Indian children would have needed to receive a dose of about 2 Gy in a relatively short time (weeks).

This would require ingestion of an enormous amount of radioactive material of the order of at least 40 GBq (i.e. 1 Curie), so the levels of induced activity would have had to be very high indeed.

3. He did not consider the photon fluxes, or the reaction cross-section required to induce those activity levels.

4. He did not attempt to identify those stable nuclei that could be made radioactive as he described. From his own reasoning it needs to be something with a relatively short half life and he could have reasoned back to what it might be if it existed.

5. If such levels of radioactivity were induced in the food, that in turn would be so radioactive that it would have produced high external doses for the people handling it.

6. Again if such levels of radioactivity were induced in food, even higher levels of induced activity would be produced in material already being sterilised (in medical supplies) and they would be very radioactive, so much so that they would give high radiation doses to people handling the sterilised goods. Film badge records at Australian plants show that this is not so.

7. A dose of 2 Gy would produce even more significant changes in lymphocytes etc (see MacPhee).

Other points that Mr Julius would appear not to have understood include:

a) sensitivity of counting procedures

In all the studies that have been made of irradiated food induced radioactivity has never been detected and instrument counting techniques are very sensitive. For example analysis of residual radioactivity at the Atomic Weapons Testing sites at Maralinga involve counting times of tens of thousands of seconds and sensitivities of fractions of a bequerel per gram. Thus any induced radioactivity could be detected easily.

b) sensitivity of instruments versus biological systems

The lower limit for biological monitors (i.e. chromosomal damage) is about 0.1 Gray wheres radiation detectors can readily measure levels of less than 1 microgray per hour.

c) possible production of metastable isomers

Mr Julius quotes one Dr Van Tuschscheerer as stating that isomer production is the only possible nuclear process

below 1 Mev, but he didn't say that it occurs. Mr Julius confuses something being possible (but never having been detected) with it actually having occurred.

d) natural radioactivity

Mr Julius dismisses natural radioactivity by saying he would like to see the evidence. There is substantial evidence in both scientific papers (Health Physics Journal, ARL reports) and books (e.g. Eisenbud - Environmental Radioactivity - third edition - Academic Press - New York 1987)

e) radiation dose rates and radiation (photon) fluxes

Mr Julius attempts to make the point that the Indian study results were not replicated by other workers because they used different radiation regimes, and by so doing used different radiation fluxes which failed to produce metastable isomers. The radiation dose rate is dependent upon the flux (number of photons or rays passing through one square centimetre per limit of time) and the energy of the radiation. The International Food Irradiation Project, which was strongly criticised by Julius, used cobalt-60, therefore the energy was the same, and a similar dose rate of 75,000 rads per hour, therefore the radiation flux was the same. Thus if any metastable isomers were induced in the Indian wheat it would also have been induced in the IFIP study, as the radiation regimes were comparable.

Conclusions

Although irradiation plants use very large radiation sources with the potential for very serious accidents, experience has shown that properly constructed, properly maintained and properly policed plants, can operate in a safe and satisfactory manner. The risk to either workers in the plant or members of the public living nearby is negligable.

In this context, properly policed means that the plant operate subject to comprehensive and specific legislative controls that ensure that operator training, control procedures, safety equipment, radiation monitors etc, are all maintained at a satisfactory high level.

Radiological safety and associated health risk are not by themselves arguments against the use of such plants for either the sterilization of medical and other supplies or the irradiation of food.

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Radiation Safety Adviser

APPENDIX 7

SAFETY CONCERNS AT STERITECH PLANT

During the inquiry a number of concerns were expressed regarding the safety aspects of the irradiation plant operated by Ansell Steritech at Wetherill Park in Sydney. The following comment outline these concerns, as listed by Friends of the Earth, and the responses by the Managing Director of Ansell Steritech and the Committees adviser on Radiological Safety.

a) *There is no power back-up for the plant - Complete reliance is placed on the force of gravity to return the Cobalt 60 source to the shielding pool. Cables can become jammed.*

There is no generator standing by as there is no need for backup. Power would only be required if there were a power failure, which is not frequently. If power does fail the plant shuts down and goes into safety mode.

Even with power available the source descends into the pool under gravity, the rate of descent being determined by the rate at which the air is allowed to exhaust from the pneumatic hoist. The usual time taken is about 25 seconds.

The arrangement is considered to be quite satisfactory as gravity is not a force that can be switched off. Cables can jam with or without a power back-up. Such a back-up would have little, if any, effect on the way such a situation would be handled. If power failed remedial action could not be taken until lighting in the plant room was available. It would be a financial liability to the company, not a radiological hazard.

b) *Small holes have been drilled through the roof to allow restricted manipulations with long handled tools. There is no remote controlled system or equipment to deal with an unshielded source.*

The source is shielded at all times either by water or concrete walls. If for some reason the source rack cannot go back into the pool and is suspended or stuck there are holes where the lead shot can be taken out and long handled tools can be used to try and free it. The chances of that happening are extremely remote. When the rack is in the up position you cannot get into the chamber, the door is electrically locked.

The source is intended to be unshielded during normal operations. If it becomes jammed and if the long handled tools can't manipulate the source back into the pool there would be time to arrange a robot with TV and/or remote arm to manipulate the source within the cell. There would not be any radiological risk to personnel whilst this was being arranged and carried out.

On two occasions the source jammed at the Dandenong plant; each time it was returned to the pool following manipulation of the hoist cable.

c) *To raise the Cobalt 60 from its shielding pool it is necessary to use a key which is attached to a geiger counter. Anyone entering the chamber is supposed to take the key and counter to prevent the raising of the Cobalt 60 by someone who did not know they were inside. However the key and counter could easily be left outside, or the key detached, with lethal misunderstanding.*

The only way to bring the source rack up is by going to the farthest corner of the chamber, inside, and throwing a switch which starts a timing mechanism in the control console. You then have to come out, close the door, hook the chain and throw another switch at the control console. The plant cannot be started up from outside.

The arrangement of a geiger counter attached to a key which is used to switch the source control on and off has been misunderstood. The geiger counter is attached to the key to ensure that people entering the radiation room after the source has been lowered into the pool have a counter with them as part of the entry procedure. It is a back-up check to the installed entrance maze monitor which in turn is interlocked to the entrance door. The key and counter being taken into the irradiation area is also part of the control procedure to prevent the source being raised whilst someone is in the irradiation area but there is also a cable running around the irradiation chamber, which if pulled, switches off the plant.

d) *People gain access to the chamber through a maze with a single chain across at about waist level. When the chain is undone this automatically activates the power supply that lifts the Cobalt 60 out. It would be simple to go over or under the chain, in which case the power supply would not be inactivated.*

The chain does not interrupt the power supply, it interrupts the supply of air to the hoist mechanism. The chain is only one of a number of procedures which have to be encountered before the plant can be started up. It is true that the operator is relied on to unhook the chain. It can be jumped over but that does not mean the source rack is going to come up. There is still need to throw the key, walk out again, go to the console and throw the key there. The human element comes into it but we rely on the operator unhooking the chain.

The chain across the maze is the fourth safety control. It was actually introduced by Ansell at their Dandenong plant and subsequently adopted by the Canadians. The power supply has to be inactivated to allow the access door to open, the chain supplements this. There would be no reason for anyone to step over the chain.

e) *The plant manager has had training on safety but the people who operate the plant have none at all. At times there is only one worker operating the whole system with no supervision or control of what goes through.*

The operator is controlling what is going through the plant as he has to load the product carriers. The system is completely automatic and nobody has to work the plant. When it is started up it just goes. There is nobody pushing buttons, unless something goes wrong, and then it automatically shuts down.

There is room for improvement in safety training. The Plant Manager has attended a suitable course and the operators have appropriate training from the Canadian representatives when new sources are being installed. This training however relates to plant operation and the automatic running of the plant.

f) *The response to almost every emergency alarm is the instruction to ring the Plant Manager. There is no apparant link up with civil or other emergency services. The whole system would be ok if nothing goes wrong.*

The plant controls are linked with the Chubb Watching Service who monitor the plant operation and require the 'Deadman' switch to be operated every hour.

It is perfectly satisfactory for the action to be 'Ring the Plant Manager' as he (or she) is the appropriate responsible person.

It was stated that the system is ok only if nothing goes wrong. It should be noted that there are several redundant safety features and the design of the plant is such that even if something does go wrong there is no immediate radiological hazard to plant personnel.

g) *The Cobalt 60 in the chamber converts air into ozone and if allowed to remain ozone would attack packaging and food, therefore it must be removed. The exhaust system ensures a complete change of air inside the chamber once every minute. However the filter system is crude, composed of a cloth filter to trap particles and a charcoal filter to chemically*

remove some of the ozone. There is no system to remove bacteria and viruses from the air discharge. As food contains large amounts of bacteria and viruses there will be huge quantities of mutated bacteria and viruses discharged into the air surrounding the plant.

At the insistence of the local Council a continuously reading ozone monitor has been placed in the exhaust stack. It is set to alarm at 1 part in 10^7 of ozone. This is the threshold limit value. The alarm is interlocked with the source and if it triggers the source returns to the pool.

The question of mutated bacterial and viruses is addressed in the body of the report. Biological filters are considered unnecessary.

h) *The plant is designed solely to give a minimum radiation dose which is not appropriate for irradiating food. The layout of the plant does not permit rotating the goods so than an even dose can be given.*

The plant is not designed to irradiate food.

i) *After 20 years Cobalt 60 is "spent". This does not mean it is harmless: it can be lethal. Proponents of food irradiation say that Cobalt 60 can be re-charged. This is incorrect. When Cobalt 60 loses its activity it does not revert to Cobalt 59 but to Nickel 60, and is therefore not in a position to be re-activated and becomes problematic nuclear waste.*

'Spent' in this sense means that a pencil is too low in radiation output to be useful for sterilisation purposes. It is agreed that it is an extremely hazardous source of radiation and will need as much care in transportation back to Canada as do fresh sources.

It is not correct to state that pencils cannot be recharged during the initial manufacture as less than 25% of the initial Cobalt-59 is changed to Cobalt 60, so there is the opportunity to reactivate the sources. Even so they will eventually become a waste disposal problem. Clearly Australia has an international responsibility to ensure that they are stored and disposed of in a safe manner when no longer in use. This would be a matter to take up with the suppliers and the supervising and licensing authority.

j) *The economic life of the rods is 20 years, yet the warranty is for only 15 years.*

All this means is that the rods will have to be decanted from the source holder and inspected very carefully for signs of corrosion towards the end of the 15 year warranty period. If they are satisfactory they can be used for another 5 years or so. This is a case of the supplier being appropriately cautious. The pencils are wipe tested every time fresh sources are loaded, which is also a check of the containment.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

MODEL FOOD STANDARDS REGULATION

S3. IRRADIATION OF FOOD

(Adopted by Council at the Hundred and First Session in June 1986)

(1) For the purpose of this regulation -

(a) 'ionizing radiation' means -

(i) electromagnetic radiations including X-rays and gamma rays;

(ii) particulate radiations including alpha particles, beta particles, electrons, protons and neutrons;

(iii) all other radiations capable of producing ions directly or indirectly in their passage through matter;

(b) 'irradiation' means the processing of food by subjecting it to the action of ionizing radiation.

(2) (a) A person shall not expose food intended for sale or intended for use in the preparation of food for sale to ionizing radiation save as expressly permitted by and in compliance with this regulation.

(b) A person shall not prepare for sale, pack for sale or sell food that has been exposed (either intentionally or unintentionally) to ionizing radiation save as expressly permitted by and in compliance with this regulation.

Provided that it shall not be an offence as defined in this paragraph to so prepare, pack or sell food that has been irradiated at a place outside the State under and in accordance with laws substantially similar to this regulation in force at that place.

(c) This regulation does not apply to ionizing radiation imparted to food by measuring instruments used for the purposes of inspection.

(3) (a) Subject to this regulation, the ionizing radiations specified in this paragraph may be used for the irradiation of food, viz -

(i) gamma rays from the radionuclides cobalt 60 and caesium 137;

(ii) X-rays generated by or from machine sources operated at an energy level not exceeding 5 MeV (Million electron Volts);

(iii) electrons generated by or from machine sources operated at an energy level not exceeding 10 MeV.

(b) Ionizing radiation that -

(i) is of a type other than a type specified; or

(ii) has an energy level exceeding that specified with respect to that type of radiation,

in paragraph (a) of this subregulation shall not be used for the irradiation of food.

(4) (a) Only the following foods may be processed by irradiation -

(i) cereals;
(ii) fruits and dried fruits;
(iii) poultry;
(iv) herbs and spices;
(v) vegetables and dehydrated vegetables.

(b) The overall average dose of ionizing radiation absorbed by a food that has been processed by irradiation shall in no case exceed 10 kGy (kiloGray).

(5) (a) Irradiation of food shall not be carried out otherwise than in an approved facility and -

(i) by or under the direct supervision of a person licensed in that behalf; and

(ii) by means of irradiating apparatus registered for that purpose,

by [the Minister under the relevant State or Territory Radioactive Substances Act].

(b) Without derogating from paragraph (a) of this subregulation -

(i) facilities referred to therein -

(A) shall be designed to meet the requirements of safety, efficacy and good hygienic practices with respect to food processing;

(B) shall be staffed by adequate trained and competent personnel;

(ii) control of the processing of food within the facility shall be carried out in accordance with the [Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods based on that of the Codex Alimentarius Commission (CAC/RCP 19-1979 (Rev. 1)) to be developed by the Radiation Health Committee of the National Health and Medical Research Council] and shall include the keeping of adequate appropriate records;

(iii) facilities referred to therein and records shall be open to inspection at all reasonable times by [the Minister, the Director-General or] an authorized officer.

(6) (a) Nothwithstanding this regulation, food shall be processed by irradiation only where such processing fulfills a technological need or is necessary for a purpose associated with food hygiene.

Food shall not be processed by irradiation as a substituted procedure for good manufacturing practices.

(b) The ionizing radiation dose applied for the purpose of irradiating food shall be the minimum that is reasonably commensurate with the technological and public health purposes to be achieved and shall be such as is in accordance with good radiation processing practice.

(c) A person shall not irradiate food for any purpose unless the irradiation of that food for that purpose and the average dose of ionizing radiation to be applied have been approved by the National Health & Medical Research Council and the irradiation is carried out in accordance with the terms and conditions of the approval.

(d) Food to be processed by irradiation and the packages and packing materials used or intended for use in connection with food so processed -

(i) shall be of suitable quality and in an acceptable hygienic condition appropriate for the purpose of such processing;

(ii) shall be handled before and after irradiation according to good manufacturing practices taking into account, in each case, the particular requirements of the technology of the process.

(7) (a) Subject to this subregulation, food processed by irradiation in accordance with this regulation shall not be re-irradiated.

This subregulation does not apply to food with low moisture content (including cereals, pulses, dehydrated food and the like) that has been irradiated for the purpose of controlling insect re-infestation.

(b) For the purposes of this regulation, food shall be taken as not having been re-irradiated where -

(i) food prepared from materials that have been irradiated at low dose levels (not exceeding in any case 1 kGy) is irradiated for another technological purpose;

(ii) food containing less than 5 per centum of irradiated ingredients is irradiated;

(iii) the required full dose of ionizing radiation is applied to the food in divided doses for a specific technological reason.

(c) Notwithstanding this subregulation, the cumulative overall average dose of ionizing radiation absorbed by a food shall not exceed that specified in subregulation (4).

(8) (a) Records required to be kept in compliance with subregulation (5) of this regulation shall include particulars as to -

(i) the nature and quantity of the food treated;
(ii) lot identification;
(iii) the process used and compliance therewith;
(iv) the overall average dose absorbed by the food;
(v) an indication whether or not the product has been irradiated previously and if so, details of such treatment;
(vi) date of irradiation.

(b) Records pursuant to paragraph (a) of this subregulation shall be kept for a period of time that exceeds the shelf life of the irradiated food product in question by 1 year.

(9) (a) There shall be written in the label on or attached to a package containing food that has been processed by ionizing radiation, in standard type of 3 mm, the words -

"TREATED WITH IONIZING RADIATION"

or

"IRRADIATED (here insert the name of the food)".

(b) When an irradiated product is used as an ingredient in another food, this shall be so declared in the list of ingredients.

(c) When a single ingredient product is prepared from a raw material which has been irradiated, the label of the product shall contain a statement indicating the treatment.

(10) A person who consigns irradiated food shall ensure that shipping documents accompanying or referring to that food include information that the food has been irradiated, the average dose, the identity of the facility where the food was irradiated, the date or dates of irradiation and the identification of the lot or lots of irradiated food in the consignment.

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