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

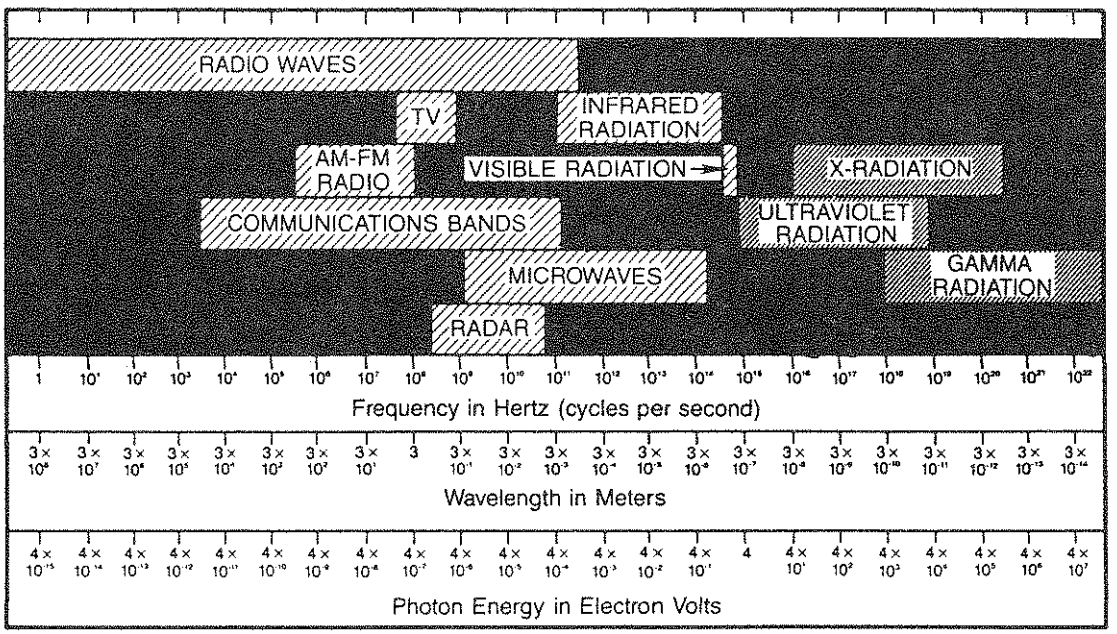
Ionising Energy

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^{o}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^{o}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 in vivo 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 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.

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.
11 Mathews, D., Submission to the Committee.
12 Tritsch, G., Submission to the Committee.
13 New Zealand Institute of Nuclear Sciences.
14 Tritsch, G., Submission.
15 Julius, H., Submissions.
16 Transcript p. 2956.
17 Pitt, J., Submission to the Committee.
18 Pitt, J., Submission.
19 Pitt, J., Submission.
20 Harris, A., Submission to the Committee.
21 McCluskey, J., Submission to the Committee.
22 MacPhee, D. and Hall, W., Advisers' Report to the Committee.
23 Tritsch, G., Submission.
24 Moore, R., Submission to the Committee.