6. NUTRITION

Introduction

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

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

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

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

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

Effect on Nutrients

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

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

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

TABLE 5
VITAMIN LOSS IN IRRADIATED FOOD

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

Source: College of Dietitian-Nutritionists in Private Practice

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

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

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

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

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

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

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

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

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

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

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

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

Significance of Changes

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

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

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

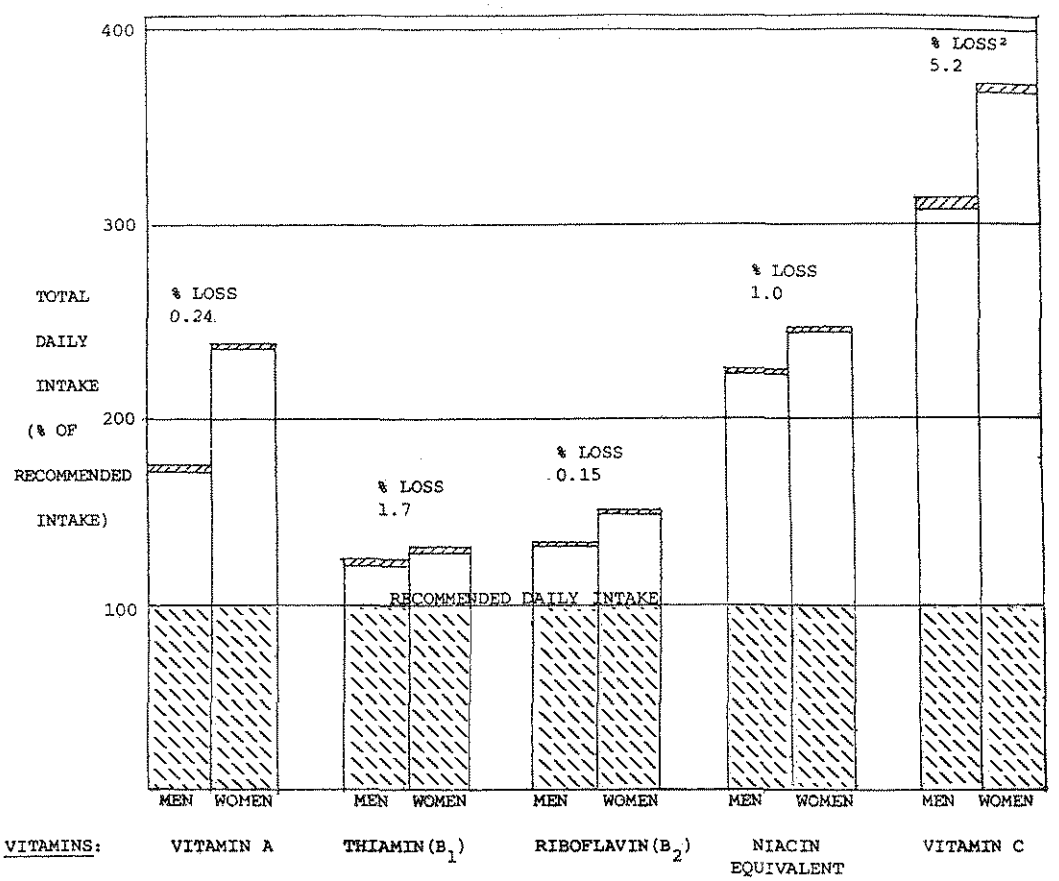
6.18 The Department of Community Services and Health advised that the National Dietary Survey of Adults published recently indicated that most Australians have access to nutrient intakes well able to meet their needs. Based on this data and assuming that 100 per cent of each of these products were irradiated,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

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

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

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

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



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

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

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

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

"At Risk" Groups

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

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

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

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

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

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

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

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

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

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

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

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

Food Intake Surveys

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

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

Conclusions

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

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

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

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

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

6.38 Accordingly the Committee recommends that:

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

6.39 The Committee further recommends that:

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

Endnote

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

7. RADIOLOGICAL AND ENVIRONMENTAL SAFETY

Radiation Dose Limits

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Radiation Levels at Australian Plants

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

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

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

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

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

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

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

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

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

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

7.21 Accordingly the Committee recommends that:

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

Staff Training

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

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

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

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

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

7.26 The Committee recommends that:

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

- **some understanding of radiation physics;**

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

7.27 The Committee further recommends that:

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

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

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

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

Plant Design

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

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

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

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

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

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

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

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

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

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

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

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

Accidents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.51 Accordingly the Committee recommends that:

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

Maximum Credible Accident

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

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

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

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

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

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

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

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

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

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

7.58 The Committee recommends that:

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

Transport, Handling and Disposal of Radioactive Materials

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

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

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

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

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

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

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

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

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

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

7.67 The Committee recommends that:

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

Radioactive Sources

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Mobile Irradiators

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

TABLE 6

RELATIVE ADVANTAGES AND DISADVANTAGES OF RADIATION SOURCES

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

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

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

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

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

7.83 The Committee further recommends that:

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

Licensing and Environmental Assessment

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

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

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

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

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

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

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

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

7.91 Accordingly the Committee recommends that:

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

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

Insurance

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

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

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

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

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

7.96 Accordingly the Committee recommends that:

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

Endnotes

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

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

8. FOOD IRRADIATION REGULATIONS

Need for Federal Controls

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

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

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

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

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

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

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

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

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

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

Model Food Regulations

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

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

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

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

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

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

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

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

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

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

8.18 The Committee further recommends that:

> the regulations require that submissions to the National Health and Medical Research Council seeking approval to irradiate a food include:
>
> - details of the purpose;
> - minimum and maximum dose;
> - data on nutritional effects;

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

Labelling

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

"TREATED WITH IONISING RADIATION"
OR
"IRRADIATED (here insert the name of the food)".

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

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

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

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

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

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

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

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

Packaging Materials

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

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

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

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

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

8.28 Accordingly the Committee recommends that:

the food irradiation regulations specify -

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

Repeated Irradiation

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

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

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

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

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

8.33 Accordingly the Committee recommends that:

the food irradiation regulations specify -

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

Dosimetry

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

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

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

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

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

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

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

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

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

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

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

Compliance

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

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

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

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

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

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

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

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

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

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

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

8.52 The Committee recommends that:

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

8.53 The Committee further recommends that:

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

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

8.55 Accordingly the Committee recommends that:

food irradiation regulations contain penalties sufficiently severe to ensure compliance.

General Agreement on Tariffs and Trade (GATT)

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

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

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

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

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

PETER MILTON
Chairman

November 1988

Endnotes

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

APPENDIX 1

LIST OF WITNESSES

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

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

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

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

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

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

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

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

APPENDIX 2

INDUCED RADIOACTIVITY

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

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

Miscellaneous Sources

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

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

Food Processing

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

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

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

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

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

Source: Council for Agricultural Science and Technology

APPENDIX 3

ALTERNATIVES TO FOOD IRRADIATION

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

Heat and cold treatment

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

The double dip hot water treatment has been accepted, only by mainland US for certain products. The US has reported many quality problems which are said to result from early harvesting. Japanese quarantine authorities do not accept that double hot water dip treatments confer an appropriate level of quarantine protection and security.

Cold storage treatments are already used as widely as practicable in Australia for the purpose of disinfestation. However the treatment is limited in its application by the cold tolerance of the product at temperatures lethal to insects. Some products suffer chilling injury which render them unmarketable. Japanese quarantine authorities will not accept the shipboard disinfestation of produce from Australia. However the practice is permitted for produce from the US.

Sterile insect release process

This involves breeding and releasing of sterile insects, resulting in non reproduction of that particular species. Fruit fly control programs have been shown to be workable alternatives to ethylene dibromide.

This is a component of some pest eradication programs leading to the status of "area freedom" from the pest concerned. Areas granted this status may export produce to the designated market without treating the produce for the insect pest concerned. Parts of Australia already have area freedom status and the sterile insect technique has been used in WA against Mediterranean Fruit Fly, an introduced pest. This method has been appraised for Queensland by scientific authorities and considered inappropriate because of the dispersal of Queensland fruit flies in natural wilderness areas. The method relies on trapping to monitor eradication effectiveness and lures are still lacking for some of the native fruit fly species. Work is still continuing in this area.

Development of disease/insect resistant plants

CSIRO has been conducting research into this area.

Disease resistance is more readily selected for in a plant breeding program than is insect resistance. This should be a long term consideration in all such programs but, regrettably, the success rate is very low even for diseases.

Modified atmosphere treatment

This process is suitable as a substitute for ethylene dibromide fumigation on grains to reduce insect infestation. Blasting of carbon dioxide or nitrogen kills the insects by depriving them of oxygen.

These techniques are already used extensively in the stored grain industry. For fruit and vegetables they are generally unsuitable because of the extended time taken to kill insects. There are complications for fruit when latent fungal infections are favoured by the modified atmosphere.

Aluminium phosphide treatment

This is a known safe alternative to ethylene dibromide fumigation in the US.

This fumigant, also known as phosphine, is widely used for disinfestation of grain. Research has shown it to be inappropriate for use on fruit against the Queensland Fruit Fly due to the damage caused to fruit at the doses required to kill the fly and the slow mode of action which requires sealing the produce for five days, followed by five days airing to disperse residual gas.

Heat sterilisation of herbs and spices

This process involves heat sterilisation with super heated steam.

Most fruits are damaged by more than a very brief time at 52^{o}C. Superheated steam would obviously be inappropriate for fruit and vegetables.

Microwave and infra-red treatment

As an alternative to the use of ethylene dibromide on stored grain microwaves to heat the grain under vacuum conditions have been used. This technique is ready for commercialisation. Heat treatment by infra-red also appears to be feasible and effective.

Early research showed these methods to have no application to fruit and vegetables for disinfestation purposes.

Sonar detection

A device called an "acoustic coupler", which can detect fruit fly larvae by the vibrations caused when the larvae eat the fruit, has been developed. Infested fruit is then removed before it is shipped.

This technique is technologically complex and still at a very early stage of development. It is theoretically desirable but will require costly refinement to develop it. The capital cost could prove to be very substantial for a central packing facility and totally uneconomic for on-farm application.

Cold storage

Increase the facilities currently available for cold storage, develop lower cost storage facilities and ensure that cold storage facilities have uniform controlled temperature mechanisms.

This facility is widely developed, down to the level of individual growers.

Better marketing strategies

Implement improved crop sowing methods to prevent over supply and plant crops at different periods to prevent simultaneous ripening.

COD is considered the industry leader in this field, with large amounts of time and money invested in promotion and marketing.

Multitherm preservation

The "multitherm" process involves rapid but even heating throughout the food. After packing the food in a plastic container, it is pre-heated, then briefly cooled, and then surrounded in a water bath and heated in a microwave oven. Finally the product is cooled to room temperature and can be stored in this state for several months. This technique does away with canning and obviates the need for freezing food. It rivals canning in its low cost and products taste fresh, even for difficult to preserve foods such as fruit and vegetables.

This technique is not appropriate to fruit and vegetables at the scale and volumes required for export marketing. The temperature aspects of the technique render it unsuitable for tropical and sub-tropical products. Cost would be a significant factor against it.

Comparative costs

It has been estimated that application of irradiation to food items will increase the cost.

Given that disinfestation treatments are essential to comply with quarantine requirements of markets, the cost of irradiation is estimated to be very comparable to EDB fumigation.

Subsequent to the above evidence PAFI provided the Committee with the following additional alternatives to food irradiation. COD or other witnesses did not have the opportunity to respond to these new processes.

Semperfresh

This is a process which uses pure sucrose esters (a derivative of sugar) as a coating on fruit and vegetables to delay ripening and extend shelf life.

Semperfresh is derived from pure food ingredients and is edible and bio-degradable. It is produced as a powder which is dispersed in water for use. When coated on the outside of fresh fruit it has the property of delaying ripening. It reportedly has been approved for use by the FDA and other international bodies.

Hydroponics

This is an application for growing fruit and vegetables and flowers in washed gravel. The produce is grown in washed gravel and enclosed in a large plastic dome. The advantages are freedom from pests and diseases, easy harvesting and large crop yields from small areas of land.

Sterispice

This is a process which utilises a pre-determined thermal sterilisation cycle combined with a coating process for sterilising herbs and spices in their original form. The disadvantages are that due to high temperatures and moisture some spices darken and there is a small loss of flavour components. The advantages are that it reduces the bacterial count to practically zero and reduces or eliminates enzyme activity.

Dry heat treatment

This is a treatment using hot forced air to disinfest fruit fly in papayas and other tropical fruits.

APPENDIX 4

AN ANALYSIS OF THE SAFETY OF FOOD IRRADIATION: GENETIC EFFECTS

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The Issues

A major concern of opponents of food irradiation is whether it is safe to consume irradiated food. No evidence of acute toxicity from the consumption of irradiated food has been uncovered so a major concern is that life-long consumption of irradiated food may lead to the ingestion of small quantities of potentially harmful radiolytic products which may accumulate in the body and thereby produce long-term adverse effects.

Three main concerns have been expressed about long term safety in the critical literature (e.g. Australian Consumers' Association, 1987; Julius, 1988; Webb and Lang, 1987). The first concern is that irradiation may produce radiolytic products in food which, if consumed in sufficient quantity, may produce changes in human genetic material (e.g. Webb and Lang, 1987), and that these changes may, in turn, lead to cancer (if the cells affected are somatic cells), or to genetically transmitted defects (if the cells affected are germ cells).

A second concern is that the process of irradiation may deplete foods of essential nutrients. Although it is conceded that this may not be a serious problem for well-nourished persons, the concern is that people whose diet is marginal, and in whom irradiated foods comprise a substantial component of the diet, may develop deficiency diseases, or a reduced resistance to infectious disease (e.g. Julius, 1988; Webb and Lang, 1987). This concern is not shared, however, by professional nutritionists who, in submissions to the Committee, have made worst case estimates

of the impact of irradiated food on the vitamin intake in the average Australian's diet and concluded that its impact will be minimal.

A third concern is with the microbiological safety of food irradiation. This covers a number of issues. One fear is that irradiation may kill harmless bacteria which provide the usual indications of food spoilage (smell, taste and appearance), thereby allowing harmful microorganisms (e.g. botulism) to grow undetected. Another is that irradiation may produce mutations in pathogenic microorganisms (e.g. *Aspergillus flavus*) which may be found in certain foods (e.g. grains and nuts). The fears here are that (i) these and other microorganisms may become radiation resistant and (ii) that irradiation of toxin-producing fungi may cause them to produce increased levels of toxins (e.g. aflatoxins) thereby increasing the likelihood of human diseases being caused by these microorganisms (Julius, 1988; Webb and Lang, 1987). Few, if any microbial geneticists share these concerns (see, for example, Forsythe, 1988).

We will therefore concentrate on the first issue in this report. Does the long term consumption of irradiated food increase the risk of occurrence of delayed genetic effects such as cancer in the case of the person consuming the food, or inherited birth defects in the case of the progeny of persons who consume the food?

Principles in the Evaluation of Safety

It is necessary to agree upon some general principles for evaluating the safety of any changes in a process which impinges upon human well-being to the extent that food irradiation might. Two separate issues need to be resolved: (1) where does the burden of proof lie, with those who argue that it is safe, or with those who argue that it is unsafe? and (2) by what standard will the claims of contending parties be evaluated? Answers have been implicitly given to both questions by opponents of food irradiation who assume that advocates of the process have an obligation to prove that it is safe beyond reasonable doubt, and hence that any doubt about the safety of food irradiation should be resolved by deciding against its introduction.

We would suggest that if the Committee decides that the burden of proof lies with those who would introduce food irradiation, then it should adopt a reasonable standard of proof. We would suggest the following principles: that the opponents of food irradiation have to provide a **prima facie** case for the process being dangerous, whereas proponents need to demonstrate that the process does not cause any of the adverse effects identified by its opponents. Any requirement that the process be safe beyond all doubt sets too high a standard, one that can be satisfied rarely, if at all, and one that must be selectively applied to new rather than to existing methods of food processing.

We suggest that those who claim that the consumption of irradiated food is a cause of genetic damage need to provide evidence:

(1) that animals fed on a diet of irradiated food have a higher rate of genetic damage than animals fed on non-irradiated food; and

(2) that there are good biological reasons for believing that the relationship is truly causal, that is, it cannot be explained in any other way.

We suggest that those who claim that the consumption of irradiated food does not cause genetic damage need to provide evidence:

(1) that animals fed on a diet of irradiated food do not show a higher rate of genetic damage than animals fed on non-irradiated food; such evidence should come from studies which have a good chance of detecting such an effect if one exists; and

(2) that there are good biological reasons for not expecting such a relationship, for example, the absence of a plausible mechanism, based upon a detailed understanding of the underlying biological processes which make the relationship an improbable one.

The disciplines of experimental design and statistical inference provide formal criteria for evaluating the adequacy of evidence in favour of the first requirement. In the case of both opponents and proponents of food irradiation these include:

(i) the requirement that animals are randomly assigned to receive either irradiated or non-irradiated food in order to minimise pre-existing differences between the animals in each condition (Fisher, 1949);

(ii) the use of reliable and valid measures of genetic damage, i.e. measures which show genetic change if it occurs, and not otherwise;

(iii) an appropriate form of statistical analysis of the data to make the hypothesis of chance an unlikely explanation of the data;

(iv) the requirement that independent researchers are able to replicate the results of the study, i.e. to obtain the same results when they repeat the experiment.

(v) in the case of studies which fail to find a a difference between animals fed on irradiated and nonirradiated food, a statistical power analysis (Cohen, 1977) is essential to demonstrate that the studies had a good chance of detecting a difference if one existed.

Expert biological knowledge about the mechanisms of genetic damage is required to evaluate the second criterion - the biological plausibility of a causal relationship, or its absence. Only someone with expert knowledge in genetics can answer the following questions: Are the measures of genetic damage (e.g. polyploidy in peripheral lymphocytes) valid and reliable? Are there any errors in experimental technique that invalidate the results? Do they results make genetic sense, i.e. are they the type of effects one would expect if food irradiation caused genetic damage ?

DOES IRRADIATED FOOD CAUSE GENETIC DAMAGE?

An evaluation of the claim that the consumption of irradiated food causes genetic damage requires an analysis of the evidence in favour, and the biological plausibility of, each step in a complicated causal chain involving at least six steps. These are that:

(i) irradiation produces genotoxic products in food which,

(ii) persist in the food long enough,

(iii) to be absorbed in sufficient quantity by the organism

(iv) to reach the DNA in the cell nucleus in their genotoxic form

(v) producing genetic damage in the DNA of exposed cells which can be converted from pre-mutagenic damage to fixed mutations,

(vi) and that any such cells either become cancerous, or else, because the changes in the DNA occur in germ line cells, are then transmitted to the next or subsequent generations.

We can evaluate this claim in two steps. First, we can ask the question: does genetic change occur at a higher rate among animals which have consumed irradiated food? If it does not, the causal claim is seriously weakened. Second, if there is no relationship between the consumption of irradiated food and genetic change, the case in favour of rejection is strengthened by showing that one or more of the events that are assumed to occur in this chain of occurrences are extremely unlikely to occur. Since a causal chain is only as strong as its weakest link, the more weak

links there are in the alleged chain, the more improbable the causal claim which is based upon it.

THE NATIONAL INSTITUTE OF NUTRITION STUDIES

The opponents of food irradiation who argue that food irradiation may cause genetic damage (e.g. Tritsch, 1988; Webb and Lang, 1987) cite evidence from a series of studies undertaken at the National Institute of Nutrition in India in the 1970's (Bhaskaram and Sadasivan, 1975; Vijayalaxmi and Sadasivan, 1975; Vijayalaxmi, 1975; Vijayalaxmi and Visweswara, 1976; Vijayalaxmi, 1978). According to Tritsch, these studies are the "most convincing and comprehensive group of studies to demonstrate the harmful effects of irradiated food" (letter May 10, 1988, p6). These studies deserve careful consideration since they seem to provide evidence that irradiated food has a biological effect which has been replicated in several animal species, including human children; and the effect appears to be on the genome of peripheral lymphocyte cells, which seems to justify concerns about the delayed genetic effects of consuming irradiated food.

In these studies, the researchers fed freshly irradiated wheat to a number of different animal species (malnourished human children, macaque monkeys, and rats) and measured the occurrence of **polyploidy** in peripheral lymphocyte cells. Polyploidy is the occurrence of multiples of the normal chromosome complement (46 pairs in humans) in the cells. The authors of these studies assumed that polyploidy was an indirect measure of genetic damage. It needs to be emphasized that this assumption means that data

cited on polyploidy do not bear in any way on the capacity of irradiated food to cause DNA damage.

Bhaskaram and Sadisavan (1975) conducted a study "to determine the effects of feeding irradiated wheat to children suffering from protein-calorie malnutrition" (p130). The subjects were 10 children aged from 2 to 5 years who were suffering from kwashiorkor and showing growth retardation. They were placed on diets of 4g protein/kg and 200 kcal/kg body weight which contained 20g wheat/kg. Five children received wheat which had been irradiated in the previous 3 weeks and another five children received wheat which had not been irradiated. The way in which the children were allocated to these two conditions is unclear; they were reported to be "divided" into two groups. Bhaskaram and Sadisavan later repeated the study in a group of children who were fed on irradiated wheat which had been stored for 12 weeks before being consumed.

Bhaskaram and Sadisavan reported that the children who had been fed freshly irradiated wheat showed an increased rate of polyploid cells in peripheral blood lymphocytes. The increase first became apparent at 4-6 weeks; it increased while the children remained on the diet, and it slowly returned to normal after the irradiated wheat was withdrawn. The group which received irradiated wheat after 12 weeks of storage showed a smaller increase in the rate of polyploidy. The findings did not show any increase in "chromosomal aberrations like breaks, gaps and deletions" (p134). Bhaskaram and Sadisavan argued that their findings "clearly indicate that the appearance of polyploid cells is due to

feeding irradiated wheat" (p134). While acknowledging that the "precise biological significance of polyploidy is not known", they argued that its occurrence was cause for concern since polyploid cells "occur in malignancy, after exposure to radiation, during viral infections, and in senility" (p134). We would add that polyploid cells are also found in normal people.

Vijayalaxmi and Sadasivan (1975) investigated "the effects of consuming irradiated wheat on bone-marrow chromosomes in well-nourished and malnourished rats" (p135). 52 weanling rats were "divided" (randomly?) into two groups, one of which was fed on a low protein diet, and the other of which were fed on a rich protein diet for 8 weeks. After eight weeks, 8 animals in each group were sacrificed to assess the effects of malnourishment on the occurrence of chromosomal breaks and deletions, and polyploid cells in bone-marrow cells. The remaining animals were assigned to one of three conditions for 12 weeks: (i) unirradiated wheat, (ii) freshly irradiated wheat, and (iii) freshly irradiated wheat plus a protein supplement of caesin. The wheat had been irradiated at 75 krad (0.75 kGy) and fed to the animals within 20 days of being irradiated.

The results showed that irradiated food increased the rate of polyploidy in both well and poorly fed animals. Malnourishment had a much larger effect on breaks and deletions than did irradiated food. They interpreted their results as showing that irradiated food caused an increase in polyploidy in peripheral lymphocytes and repeated their previous remarks that it was difficult to suggest a

mechanism for the effect, "the precise significance" of which was "not clear" (p141).

Vijayalaxmi (1975) performed two linked studies in Wistar rats which examined the effects of consuming irradiated wheat on the occurrence of polyploidy and chromosome breaks in bone marrow cells. In the first study, 30 rats were assigned to one of three conditions for 12 weeks: (i) unirradiated wheat, (ii) freshly irradiated wheat, and (iii) stored irradiated wheat. In the second study rats were fed on freshly irradiated wheat and 6 animals were sacrificed at the end of 1,2,3,4,6,8 and 10 weeks in order to see what duration of consumption was required to increase the rate of polyploidy. Neither study showed any effect on the rate at which chromosomal breaks and deletions occurred. The results for polyploidy confirmed the earlier findings: only the animals fed on freshly irradiated food showed an increased rate of polyploidy, and, in the second study, the increase in the rate of polyploidy was not detectable until the animals had been on the diet for 6 weeks.

Vijayalaxmi (1978) carried out a similar study using *Macaca mulatta* monkeys as experimental subjects. 21 monkeys were assigned to receive one of the following diets for 10 months: (i) unirradiated wheat, (ii) freshly irradiated wheat, and (iii) stored irradiated wheat. She measured the occurrence of polyploidy and chromosomal breaks and deletions. There were no differences in the rates of chromosomal breaks and deletions but agian there were differences in the rate of polyploidy: only animals fed on

the freshly irradiated wheat showed an increased rate of polyploidy.

Vijayalaxmi and Visweswara (1976) supported the findings of the studies of polyploidy by conducting a study of the effect of freshly irradiated food on dominant lethal mutations in rats. In this study, male Wistar rats were fed on either a good or a poor diet for 8 weeks and then 4 animals from each group were mated with 3 virgin females per week for 4 weeks in order to see what effect a low protein diet had on male reproductive performance. The latter was measured by a "mutagenic index" which was the ratio of dead embryos to total implants. This index was based on the assumption that the occurrence of mutations would produce an increase in the mortality of embryos after implantation in the uterine lining. The remaining animals were fed on either irradiated or nonirradiated wheat for 12 weeks before being mated with 3 virgin females per week for 4 weeks. Vijayalaxmi and Visweswara reported a higher mutagenic index among the offspring of animals which had been fed upon the irradiated wheat.

AN EVALUATION OF THE NIN STUDIES

We need to consider four things in evaluating the safety of the NIN studies: (i) were the experimental designs and statistical analyses adequate? (ii) to what extent have their results been replicated by other researchers? (iii) were the experimental methods, e.g. choice of measures, appropriate? and (iv) how biologically plausible are the results? Answers to the first two questions enable us to decide whether the consumption of irradiated food does or

does not have a reproducible biological effect. Answers to the third and fourth questions enable us to decide whether any such effect is a biologically important one.

(i) Experimental Design and Statistical Analyses

The experimental designs of each of the NIN studies appear to be adequate in that the choice of conditions under which the animals were observed (on diets of irradiated and nonirradiated wheat) provided an opportunity to answer the question: does a diet of irradiated wheat increase the rate of polyploidy? The authors do not clearly state that the animals were **randomly** assigned to receive either freshly irradiated food or not but they may be given the benefit of the doubt since the importance of random assignment to groups is widely understood in experimental science.

The major difficulty in evaluating the quality of the statistical analyses is that they are inadequately reported. In some of the studies (e.g. Bhaskaram and Sadisavan, 1975; Vijayalaxmi, 1975) it is impossible to judge the adequacy of the analyses because the experimenters do not describe the statistical analyses that were conducted. Additionally, in each of these experiments insufficient data are reported for an independent analysis to be performed. The statistical analyses of the other studies (e.g. Vijayalaxmi, 1978; Vijayalaxmi and Visweswara Rao, 1976) seem to be more appropriate. On the whole, the NIN investigators standards of statistical reporting are less than satisfactory but it is arguable that they were no worse than many other studies in the toxicological literature at the time. The consequence of the poor standard of statistical reporting is that we are

not able to make confident judgements about whether their data support their conclusions.

(ii) Replicability of Findings

The most serious concern about the NIN studies has been the mixed outcomes of attempts by other researchers to replicate their results. Several investigators have failed to replicate the NIN results in the same species (Chauhun, Aravindakshan, Kumar, Rao, Aiyay and Sundaran, 1977; Reddi, Reddy, Ebenezer and Naidu, 1977; Tesh, Davidson, Walker, Palmer, Cozens, and Richardson, 1977) while one other investigator has reported similar results in a different species (Renner, 1977).

Replication of findings is the gold-standard of dependable data in science (Fisher, 1949; Tukey, 1986). The consequence of a failure to meet this standard is doubt about the credibility of the research findings. In the case of a single result, a consistent failure to replicate in well-controlled studies suggests that the positive result was due to chance. In the case of a series of studies, as in the NIN case, the failure of independent investigators to replicate suggests the possibility of experimental error or consistent confounding.

Failed Replications

Four groups of investigators have failed to replicate one or more of the NIN studies on polyploidy (George, Chaubey, Sundaram and Gopal-Ayengar, 1976) or dominant lethal assay (Chauhun et al, 1977; Reddi et al, 1977) or both (Tesh, Davidson, Walker, Palmer, Cozens, and Richardson, 1977). One further group whose work is often

cited as a successful replication (Anderson, Clapp, Hodge and Weight, 1981) are also included here for reasons given below.

George et al (1976) conducted a series of three experiments on the frequency of polyploid cells in the bone marrow cells of Wistar rats which had been fed on freshly irradiated wheat. In the first experiment six animals were either fed on freshly irradiated wheat or not. In the second experiment, a more complicated experimental design was used to examine the effect of adding irradiated wheat to diets with varying constituents. In the third experiment a single group of rats was fed irradiated wheat within 24 hours of irradiation and levels of polyploid cells in their bone marrow were compared to those in the control condition in the first experiment. In none of these experiments was there an increased rate of polyploidy in the animals fed on the irradiated wheat. The differences in the rates of polyploidy in each case were very small (0.21 ± 0.05 versus 0.25 ± 0.04 in the first experiment and 0.28 ± 0.03 in the third experiment). With only six animals per group, however, the chances are high that a small difference may have escaped detection.

Chauhun et al (1977) conducted three sequential experiments to examine the effects of feeding freshly irradiated wheat on the dominant lethal assay test in Wistar rats. In the first experiment they examined the acute effects of feeding rats on irradiated wheat (within 24 hours of irradiation) for 7 days. In experiment two they fed rats on irradiated wheat for six weeks and in experiment 3 they

extended this period to 12 weeks. At the end of the feeding period in each experiment, the male rats were mated with three virgin female rats for 7 days, and then with three new females for 5 weeks in experiments 1 and 2, and 8 weeks in experiment 3. The females were killed 11 days after mating and the number of live and dead implanted fetuses were counted. The test (irradiated diet) and control (nonirradiated diet) animals were compared on five measures of reproductive outcome. The only statistically significant differences between the groups in the large number of statistical comparisons that were performed in these experiments favoured the control group (i.e. showed lower rates of adverse outcomes in the control group). There are two reasons why it is unlikely that these failures to replicate are attributable to lack of statistical power: first, more animals were studied, over a longer period of mating; and second, these animals were fed on irradiated wheat within 24 hours of irradiation whereas the NIN animals had been fed on irradiated wheat within 20 days of being irradiated.

Reddi et al (1977) used the dominant lethal assay in male and female mice to assess the cytogenetic effects of irradiated wheat. They conducted separate dominant lethal assays in male and female mice comparing animals which had been fed on one of the following: a control diet; a diet consisting of wheat irradiated at 20 krad; and a diet of wheat that had been irradiated at 200 krad. After being fed on these diets for 180 days, male mice were mated with virgin females. Half of the females were allowed to litter

and the rest were killed at 14 days gestation. The outcomes assessed in those allowed to litter were: litter size, sex ratio, and growth rate. The outcomes assessed in those that were sacrificed were: pre- and post-implantation loss, and total fetal loss. In the study of female dominant lethal assay, all females were sacrificed after 14 days and assessed for pre- and post-implantation and total fetal loss. There was no evidence of differences between the progeny of male mice fed on the three diets on any of the measures of outcome, and no suggestion of dose-response relationships which failed to achieve statistical significance. The same results were observed among the progeny of the female mice.

The study of ***Anderson, Clapp, Hodge and Weight*** (1981) is usually quoted as a successful replication of the NIN study of dominant lethal assay but we believe that this interpretation is mistaken so it is included under failed attempts to replicate.

Anderson et al conducted a series of four studies on the effects of consuming irradiated food on the dominant lethal assay in mice. In these experiments, male mice were fed on three different types of laboratory diet, which had been irradiated or not. In several experiments three doses of irradiation were studied (1, 2.5, and 5 megarads); in another the food had been stored before consumption or not; and in two studies a "positive control" was included, i.e. a group of animals was given a chemical which was a known mutagen (cyclophosphamide) to demonstrate that the experimental system was sensitive to the effects of a known

mutagen. The male mice were fed on the irradiated or nonirradiated diets for 3 weeks and then mated with 3 virgin females for each of eight weeks. The positive controls were fed on nonirradiated food and injected with the cyclophosphamide 2 hours before the first mating. The outcomes measured were the number of implanted fetuses and the number of early fetal deaths at 14 days after mating.

The results clearly showed that the cyclophosphamide produced a decrease in the number of implanted fetuses and an increase in the rate of early deaths during the first three weeks post-injection. This effect was consistently observed in the three experiments which included this positive control. By contrast, there were a small number of statistically significant differences in the groups that were fed on the various irradiated diets (6 out of the 84 or more tests conducted) but these were consistent with the effects of chance. The pattern of differences showed neither consistency across weeks within studies nor between studies (they occurred in weeks 4, 7 and 8 in different studies and there were no consistencies in the different diets). Even more disturbingly, there were no consistent effects of storing the food on either measure: it made no difference at all to the total number of implants per pregnancy, and the only difference in the rate of early deaths showed a lower rate in the freshly irradiated wheat!

The studies of ***Tesh, Davidson, Walker, Palmer, Cozens, and Richardson*** Tesh et al (1977) are the most convincing of the attempted replications of the *NIN* studies. These studies, which were conducted at the request of the European

Food Irradiation Project, attempted to replicate the results of the NIN studies of polyploidy and dominant lethal assay. Two independent scientific laboratories attempted to replicate the Indian study using Wistar rats as the experimental animals. Sex-matched litter-mates were randomly assigned to one laboratory or the other, and the animals in each laboratory were fed on a diet which came from the same source. These precautions were taken to reduce the possibility of the results being peculiar to a single laboratory.

In the first study of bone marrow polyploidy, the animals in each laboratory were randomly assigned to receive a diet of either nonirradiated wheat, or a diet of irradiated wheat 2, 4, or 8 weeks after being irradiated with 75 krad. Only the results for the animals fed on the freshly irradiated wheat are reported. The other groups were included to examine the possibility of a dose-response relationship if the irradiated wheat had produced an increase in the rate of polyploidy.

In the course of this experiment one of the experimental diets was unaccounted for and there is the possibility that it may have been fed to the control animals. The researchers continued the study but added an additional control group to control for the effects of this possible error in the allocation of irradiated wheat to the controls.

A notable feature of the Tesh et al studies was that the experimenters included a double-blind assessment of the occurrence of polyploidy by two independent observers

(readers 1 and 2). That is, the occurrence of polyploidy in each preparation was independently assessed by two observers who were unaware of which condition the animal had been studied. This precaution was introduced to examine the degree to which different observers were able to agree upon the presence or absence of polyploid cells.

The results failed to show any increase in the rate of bone marrow polyploidy among the animals which had been fed on irradiated wheat. There was no suggestion that an increase in polyploidy went undetected: the mean difference in the rate of polyploidy was very small. The mean rates of ploypoloidy were 0.095% in the control condition and 0.104% in the irradiated condition (these are the weighted means for each condition averaged across both of the readers).

Because the result was negative it is necessary to examine the statistical power of the Tesh et al study in comparison to that of the NIN studies. Detailed power calculations, which are shown in Appendix A, indicate that Tesh et al's study had at least a 96% chance of detecting a difference as large as, or larger than, that detected in the Vijayalaxmi (1978) study (0.04% vs 0.58% rates of polyploidy respectively). In addition, the results in the control group fed non-irradiated wheat which was added after the diet went missing were not statistically significantly different from those of the control group which may have inadvertantly been fed one batch of irradiated wheat.

The study of the inter-observer agreement in the assessment of polyploidy showed there was poor agreement between the two observers on the rate of occurrence of

polyploid cells in the bone marrow. The two readers produced estimates of the incidence of polyploidy which consistently differed by a factor of two or more. This suggests that judgements of polyploidy are susceptible to observer error, which is a substantial fraction of the difference observed between irradiated and unirradiated wheat in the NIN studies. For example, the NIN investigators reported rates of polyploidy 0.58% in the group that consumed irradiated wheat and 0.04% in the control group, while Tesh et al reported a difference in the estimated rate of polyploidy between the two observers of 0.15% and 0.05% respectively. Even the level of agreement about either the presence (52%) or absence (58%) of one or more polyploidy cells was only slight. (Cohen's kappa measure of agreement (Feinstein, 1985, p185) was a very low 0.09). The poor level of agreement on the occurrence of polyploidy demonstrates the necessity for "blind" evaluation of polyploidy in order to eliminate the possibility that the expectations of the observers produced spurious differences between conditions. This precaution was not followed in any of the NIN studies.

The second study of Tesh et al was conducted in parallel with the first. The same animals were also assessed for the "incidence of micro-nucleated polychromatic erythrocytes" in their bone marrow cells. There were no differences between the experimental and control animals, and the average results overall were within the reference range for the laboratory. This negative result is important since this technique is regarded as a much more meaningful

and sensitive test for genotoxins than is the induction of polyploidy.

In the third study Tesh et al attempted to replicate the findings of the Vijayalaxmi and Visweswara Rao (1976) study using the dominant lethal assay. In this study 75 male rats were assigned to one of five conditions: control (unirradiated wheat), a single short exposure to irradiated wheat followed by recovery, and three groups fed on irradiated wheat 2, 4 and 8 weeks after it was irradiated. Each male was mated with 2-3 virgin females for 10 weeks (except for group 1 which was only mated for 6 weeks). Multiple endpoints were assessed, including fertilization index, morula and blastocyte indices, pre-implantation loss, number of corpora lutea, and post-implantation loss. They also examined mortality, food consumption, body weight gain and mating performance.

The results showed some variation between the groups in these outcomes but this was unrelated to exposure to irradiated wheat, nor did the pattern of results resemble that observed by Vijayalxmi and Visweswara Rao (1976). The failure to find any such effects is especially noteworthy for a number of reasons. The effect observed by Vijayalxmi and Visweswara was a large one and Tesh et al used four times as many animals as Vijayalxmi and Visweswara so that the chance of any major effect having gone undetected is small. In addition, Tesh et al measured a great many more indices of reproductive performance, and they studied their animals over a 10 week rather than a 4 week mating period,

thereby increasing their chances of finding an effect, if indeed one existed.

Successful Replications

The only reportedly successful replications of the NIN studies have been studies of polyploidy (Anderson et al, 1981; Renner, 1977). Since the Anderson et al study has been discussed above, only the Renner study will be considered here.

Renner studied the effects of a diet of irradiated wheat on the occurrence of chromosomal breaks and polyploidy in the bone marrow of Chinese hamsters. Animals were randomly assigned to one of three groups: a control diet; a diet of irradiated wheat for 24 hours; and a diet of irradiated wheat for 6 weeks. Renner took care to check the validity of his cytogenetic methods against those of other laboratories and he ensured that readings of polyploidy and chromosomal breaks were made "blind". He also included adequate samples of animals in each condition (25, 26, and 25 respectively). He failed to find any evidence of differences between the three conditions in chromatid gaps or breaks but there were differences in the rates of polyploidy (0.06%, 0.27%, and 0.32% respectively). Renner followed up the significance of the polyploidy in a series of other experiments the details of which are not reported. According to Renner, these subsequent studies suggested that the effect of irradiated wheat on polyploidy showed a dose-response relationship in the range of 1 to 4 Mrads, and disappeared after the wheat had been stored for 6 weeks.

Summary of replicability: Given the conflicting results it seems difficult to make any summary statement about the extent to which the NIN results have stood the test of replicability. The replicability of the dominant lethal assay is the most doubtful. Other researchers have been unable to replicate the result on dominant lethal assay despite using larger groups of animals, which have been mated over longer periods, and which in some cases were fed on even more freshly irradiated wheat than that used by the Indian investigators. The standing of the polyploidy finding is less clear because well-controlled studies have obtained both positive (Renner, 1977) and negative results (Tesh et al, 1977). The latter conflict in findings suggests that, if there is a real effect, it may depend upon some unusual features of experimental design (e.g. the protocol adopted or experimenter inexperience with the normal incidence of polyploid cells, especially in bone marrow).

(iii) Substantive Criticisms of the NIN Studies

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

Evidence on the first matter was given by Dr Ruth Moore, an expert witness in the field of cytogenetics (Hearings, 15th April, 1988). She argued that the technique used by the investigators to fix the peripheral lympocytes for cytogenetic analysis was likely to produce spuriously high estimates of polyploidy, and had for this reason been

abandoned by cytogeneticists. She also argued that the NIN results were vitiated by errors in experimental technique since the rate of polyploidy observed in the group that consumed irradiated food were within the range of subjective error whereas those in the control group were suspiciously low (namely, zero). Other commentators have made the same point (e.g. Brynjolfsson, 1986).

The second objection to polyploidy is more fundamental, namely, that it is a poor indicator of genetic damage, even when it is measured accurately. Dr Moore, for example, argued that polyploidy occurs for a variety of reasons that are unconnected with radiation damage, e.g. as a part of the normal process of cell development in the case of megacaryocytes. She argued that a more appropriate measure of genetic damage was the occurrence of an increase in chromosomal breaks and deletions. ***It is noteworthy that although these structural chromosomal abnormalities were assessed in the NIN studies none of the studies observed any increase in such abnormalities. Nor did any of the attempted replications which also measured breaks and deletions (e.g. Renner, 1977).***

(iii) Biological Implausibility

A major problem with the results of the NIN studies is that their findings are biologically implausible given what is known about the radiolytic products and the processes of normal cell metabolism. The major implausibility is that although irradiation produces chemical changes in food, these chemicals occur in extremely small quantities, have

short half-lives, and occur in much larger quantities in other food and endogenously in body cells.

The major radiolytic products about which opponents of food irradition appear to be most concerned are hydrogen peroxide, superoxide radicals, and oxygen radicals, and some of their reaction products, such as hyderoperoxides. Those who are concerned about these chemicals seem to have overlooked the fact that *all* of these chemicals are present in a wide variety of foods at significantly higher concentrations than those which are produced by food irradiation using the relatively low doses (less than 10 KGy) which are likely to be used in practice.

More importantly, hydrogen peroxide and superoxide are continuously generated within human cells and subcellular organelles (e.g. peroxisomes) as a side-product of cell metabolism. These molecules are, in turn, the major sources of oxygen radicals within the bodies of animals and humans. One of the important bodily defenses against bacterial infection is a high level oxygen radical burst following phagocytosis of certain types of potentially harmful bacteria. The oxygen radicals kill the bacteria but not the human cells, which demonstrably have significant capacity for defense against oxygen radicals.

Because animal metabolism is basically an oxidative process, the generation of the inorganic molecules noted above is an essential feature of life. *All* organisms have accordingly evolved strategies for coping with the potential harm that constant exposure to oxygen radicals may pose. The sorts of interactions between oxidative radicals, for

example, and organic molecules which might be expected to occur in irradiated food are found both in food treated in other ways, and in the cells of living animals. More importantly, many enzymes protect cells from oxidative damage, examples including superoxide dismutase, glutathione peroxidase and the glutathione transferases. Such enzymes have to be present in all organisms which depend on oxygen for their existence in order to deal with oxidative damage, as indeed do enzymes necessary to remove the oxidative damage from DNA which also occurs on a regular basis. Recent evidence suggests that the metabolic rate of different animal species determines (i) the amount of oxidative damage per day which their DNA will receive, and (ii) the amount of oxidative damage which therefore has to be removed daily to avoid harmful long term effects.

The conventional argument that we cannot rely on information obtained in animal experiments to provide information about the effects of irradiated food on man has much less validity than may be anticipated for other types of chemicals. This is so for several reasons already outlined, namely, the universality of oxidative damage, the fact that it is caused by simple inorganic molecules rather than organic man-made chemicals, and the evolution of mechanisms in all cells to protect DNA from internally generated oxygen radicals by constantly monitoring for oxidatively damaged DNA bases and removing them. Given the 24 hour-a-day production of significant amounts of oxygen radicals and other oxidative species within man and other animals, it is extremely implausible that the minute

additional contribution which might be made by consuming irradiated food could significantly alter the course of the natural events in living cells - especially at the genetic level.

For all these reasons, the fact that no reproducible evidence of adverse effects appears to have been found over many years of experimentation is entirely consistent with what is known about the chemical charges which result from food irradiation.

OTHER EVIDENCE OF SAFETY

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

Chinese Feeding Studies

The results of the majority of the Chinese studies are unfortunately only reported second hand by Brynjolfsson (1986) who attended a Conference on food irradiation in Shanghai in April 1986. According to Brynjolfsson, the Chinese investigators have conducted a large series of studies in human volunteers in which a wide variety of biological indices, including polyplpoidy. have been measured. In none of these studies has any effect of consuming irradiated food been observed. The most convincing study was one on volunteers who were fed for 13-15 weeks on a diet which consisted of wholly irradiated diet. In all of these studies the incidence of polyploidy was measured; in

no study did it occur at a higher rate among those who were fed on irradiated food.

We have been able to review one of the Shanghai feeding studies which has been published in an English language journal (Shanghai Institute of Radiation Medicine, 1987). In this study 70 volunteer medical students were randomly assigned to receive an irradiated or non-irradiated diet comprising 35 different food stuffs for 90 days. The foodstuffs which were irradiated at doses between less than 1 and 8 KGy, comprised 60% of the volunteers' diet throughout the 90 days of the experiment. The study was conducted under double-blind conditions, i.e. neither the volunteers nor those assessing their health were aware of which diet they were receiving. A wide variety of medical endpoints were measured (e.g. body weight, blood and urine, EKG), including polyploidy, sister chromatid exchanges, and the Ames test for mutagenicity of the subjects' urine collected over a 24 hour period. Two of these measures (blood urea nitrogen and polyploidy) showed significant changes over the period of the study but neither pattern of change was consistent with an effect of consuming irradiated food. The blood urea nitrogen result, for example, arose because the irradiated group mean was below that of the unirradiated group mean ***before*** the experimental diet was introduced; the means for both groups were not statistically significantly different at the end of the 90 day trial. In the case of polyploidy, ***both*** groups showed an equal and significant increase in the rate of polyploidy over the course of the study.

Walter and Eliza Hall Institute

Three witnesses from the Walter and Eliza Hall Institute described the Institute's experience with breeding and raising 61 generations of mice which have been fed exclusively on a diet of irradiated food. Although it did not come from the results of a formally designed scientific experiment, their evidence was valuable for the following reasons. First, the researchers had no interest in promoting food irradiation. Second, their animals were fed exclusively on food which was more heavily irradiated than the food which is proposed for human consumption. This is because irradiation is used to *sterilize* the food so that animals are raised which have not been exposed to any micro-organisms that will affect the functioning of their immune systems. Third, because of the high doses and the fact that irradiated food comprises the entire diet of the animals throughout their development, any major genetic effects should be detected, if they occur. Fourth, although a control group of mice was not included, the central focus of research interest at the Walter and Eliza Hall Institute whould allow even small increases in the rates of cancers or birth defects to be detected. The main interest of researchers at the Institute is the functioning of the immune system of their experimental animals and also the occurrence of tumors. Accordingly, the occurrence of unusual rates of either of these effects in their animals would be of particular concern to them, especially if they were occurring at a higher rate than observed among studies emanating from laboratories that used heat sterilzation of

food. Fifth, detailed records have been kept of the fertility of these mice, and of the rates of malformations among animals born in the colony, so that any such effects would also have been detected. Sixth, 61 generations of mice have been reared on this diet, (i.e. several million animals), so that a reasonable opportunity has been provided for the detection of any transmissable genetic defects that may be caused by irradiated food.

Conclusions

The claim that the consumption of irradiated food causes genetic changes has not been substantiated. Nor has a *prima facie* case been presented in its favour.

The strongest evidence in favour of the claim is very weak, the occurrence of polyploidy in bone-marrow or peripheral lymphocytes in organisms fed on freshly irradiated wheat, as reported by the National Institute of Nutrition. There are several reasons to doubt the import of these findings. First, there are doubts about the reliability of the phenomenon, in that other researchers have been unable to replicate the NIN results. Secondly, polyploidy appears to be a poor indicator of genetic damage; it may arise for a variety of reasons which are unconnected with radiation exposure, including poor experimental technique. Third, there are major biological implausibilities in the chain of occurrences which allegedly links the consumption of irradiated food with the occurrence of genetic effects.

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APPENDIX A:

Power Calculations of Tesh et al Study of Polypoidy

Four quantities are required for a power analysis, namely, the size of effect (ES) which is to be detected, the number of subjects studied (N) the type 1 error rate, and the desired power (the probability of detecting a difference if one exists). In the present case, N and the type 1 error rate are fixed and we need to have an estimate of the ES in order to estimate the achieved power. To obtain the ES we need to know the average difference between conditions (irradiated and nonirradiated diets) and an estimate of the variation in this measure.

An estimate of the size of effect to be detected was obtained from the Vijayalaxmi (1975) study. In this study two groups of 10 rats were fed on either freshly irradiated or nonirradiated wheat for 12 weeks before the occurrence of polyploidy was measured in their bone marrow. Vijayalaxmi reported that the difference between these two groups of 0.58% and 0.04% polyploid cells was "statistically significant". They did not report either an estimate of variability in this measure, or the statistical test they used. A conservative estimate of the standard error of the mean can be obtained if we assume that the difference between these means was just statistically significant by a

t-test at $p < 0.05$ as follows:

$$t_{observed}\ (18df) = [(0.58 - 0.04)/\ SE_m] \geq t_{0.05}\ (18df)$$

i.e. $SE_m \leq 0.025$

(where $t_{observed}$ (18df) is the obtained value of t with 18 df, SE_m is the standard error of the mean, and $t_{0.05}$ (18df) is the critical (95th percentile) value of t with 18df.

Since $SE_m = \sqrt{s^2\ (1/N_1 + 1/N_2)}$ it follows that:

$$s \leq 0.58$$

and the standardised difference between means

$$ES \leq 0.54/0.58$$

i.e. ≤ 0.94

or approximately 1.0 in round figures.

Since the number of animals observed under each condition was unequal, a weighted mean sample size is used (28 in this case). Referring to Cohen's (1977) power tables (table 2.3.5, p36) reveals that a comparison involving a weighted mean sample size of 28 provides at least a 96% of detecting a ES of 1.0 or greater with a type 1 error rate of 0.05.

APPENDIX 5

BOTULISM RISK

Introduction

There are seven immunologically distinct kinds of Clostridium botulinum, Types A through to G. All can produce lethal toxins under certain circumstances. The spore-forming bacteria are found in soil and water environments and grow best in anaerobic environments. Types A, B, E and F can cause human botulism. Proteolytic A and most B and F strains do not grow below 10°C so that meat or fish spoilage is obvious and protein foods will be rejected on these grounds. Non-proteolytic E and some B and F strains grow at lower temperatures down to about 5°C although type E will grow at lower temperatures (down to 3.3°C) under specialised laboratory conditions. Type E toxin is easily inactivated by heat and botulism does not seem to have been associated with eating cooked fish, although botulism outbreaks have been traced to eating uncooked, smoked, salted, fermented or canned seafood fishery products such as tuna.

The possibility of increased risk of botulism has often been raised as new technologies have been introduced, such as vacuum packaging in the late 40's, cooking liver sausage in Saran film (50's), new thermal process for producing shelf-stable canned hams (60's), reduction or elimination of nitrites from cured meats (70's). In all cases the anticipated problem did not eventuate, (Tompkin, R.B. (1986) Food Technology, 40, 172).

Perceived Problem for Radiation Treatment of Fish

When fish are exposed to low doses of radiation to extend their shelf-life, the radiation sensitive bacteria which normally cause spoilage are considerably reduced in number. The public health concern is that under these conditions the more radiation resistant Type E Clostridium botulinum, if present, would grow faster than the organisms which remain and toxin could be produced before the fish is rejected because of obvious spoilage.

Current Regulatory Status

The FAO/IAEA/WHO Joint Expert Committee on the Wholesomeness of Food Irradiation at its meetings in 1976 and 1980 examined the results of extensive relevant investigations carried out from the 1960's onwards, mainly in the UK and the US. For these investigations different species of fish were deliberately inoculated, generally with large numbers of Cl. botulinum spores, irradiated and stored under different conditions until spoilage and/or toxin was produced. The Committee concluded that lean fish could be safely consumed after irradiation at a dose of up to 2.2 kGy with subsequent storage at a temperature of 3.3°C and cooking.

These conditions are set out in an annex to the WHO Codex Alimentarius Commission's Recommended International Code of Practice for the Operation of Radiation Facilities used in the Treatment of Foods.

Risk Assessment

The question of a potential botulism hazard arising from eating irradiated fish is therefore only relevant if the known safe conditions are intentionally or unintentionally altered. These could be a change in the packaging, for example, modified atmosphere storage, temperature abuse, or the use of higher radiation doses.

Several factors need to be considered:

- frequency of occurrence of the organism in the product;
- growth conditions required to give lethal toxic doses;
- whether, under these same growth conditions, other microbial spoilage will occur with sufficient production of off-odours to ensure rejection of the product on sensory grounds, and
- whether the product will be cooked before it is eaten to ensure inactivation of the toxin.

Incidence of Cl. Botulinum Type E in Fish or Aquatic Environments

Two relatively small surveys, 21 samples in 1951 and 528 samples in about 1970, failed to isolate Type E from muds, cultivated soils, fish intestines and potato washings collected from NSW, Queensland and Tasmania. Dr J Christian, CSIRO Division of Food Research concluded that "it cannot be assumed that Cl. botulinum Type E is absent from the coastal environment of South East Australia... an extensive survey involving a great many samples may be required to demonstrate the presence of Type E organisms on this continent" (Christian, J. IAEA Tech Report Ser 125 (1971) p. 76). Although Type E was suspected, but not confirmed, of causing two cases of botulism traced to Australian canned tuna (Bennett, N, et al, Med. J. Aust. 1, 804 (1968), it has not been implicated in recent cases of infant and animal botulism in NSW or isolated from the urban and rural environments associated with these cases (Murrell, W.G. and Stewart, B.J. Med J Aust 1, 13 (1983).

By contrast, Type E has been isolated from fish or from coastal or pond sediment samples obtained from several northern hemisphere countries, eg Japan, US, USSR, Denmark, UK. The incidence is extremely variable and generally too low to warrant routine sampling. Where contamination does occur, the degree of contamination in fresh fish is also low, certainly less than one spore per gram and possibly less than one spore per 10 gram of fish.

Growth and Toxin Production

Several factors influence these rates of reaction including:

- fish species (higher in some fatty fish);
- contamination level (higher in deliberately contaminated (10+/g) experimental batches);
- storage temperature, with rates increasing as the temperature exceeds about 5°C;
- packaging (generally, but not always, increased with vacuum packaging compared with oxygen-permeable films);
- radiation dose (there is some evidence that Cl. botulinum Type E spores are injured at 3 kGy and do not grow at 10°C (Rowley, D.B. et al. J. Food Sci 48, 1829 (1983); at lower dose of 2 kGy, toxicity occurred before spoilage at 7.8°C for oxygen-permeable haddock fillets inoculated with 104/g spores, but not at a lower inoculum of 100/gram (Eklund, M.W. (1982) Food Technol. 36 (12) 107).

Packaging Atmosphere

Vacuum-packaging and modified atmosphere storage of fish have also been considered as preservative techniques with a potential hazard for botulism. CSIRO food scientists Eyles and Warth have made an assessment of this risk for vacuum-packaged fish (Fd Technol Aust 33, 574 (1981). They looked at the occurrence of Cl. botulinum in fish and fish products, growth and toxin production in vacuum-packaged raw fish, human susceptibility to toxins (minimum lethal dose), destruction of toxins by cooking. They concluded that the risk of botulism is extremely small and stated:

"The consideration is not one of reducing known botulism from fish but one of assuring its continued prevention. As long as vacuum-packed raw fish are handled with the same precautions that apply to other fresh fish, and proper instructions for handling of the product are prominently incorporated into the labelling, the risk of an outbreak appears remote".

Conclusion

A similar rationale and conclusion that the risk of botulism is extremely small can be made for low dose radiation treatment of fish. In comparison with other countries, the natural incidence of Clostridium botulinum Type E in the Australian environment, should it even be present, must be very low as the organism has not yet been isolated from at least 600 samples tested. The growth rate for low concentrations of spores is very slow. Cooking destroys toxin and even in countries with a comparatively high incidence of

Cl. botulinum Type E, no cases of botulism have ever been associated with fish cooked before it is eaten. Prominent labelling should provide warnings against improper storage. The use of shelf-life date stamps and time-temperature monitors during fish distribution could be considered.

Source: Australian Nuclear Science and Technology Organisation

APPENDIX 6

HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON ENVIRONMENT, RECREATION AND THE ARTS

INQUIRY INTO THE USE OF IONISING RADIATION

ADVISERS REPORT ON RADIATION SAFETY

Introduction

Amongst the various concerns expressed about the use of ionising radiation for the sterilization of various products in general, and the irradiation of food in particular, are the risks to the workers at irradiation plants, the hazards to members of the public, and the dangers of environmental contamination.

This report addresses some of these specific concerns. It reviews current safety procedures at the existing Australian plants used for the irradiation of medical supplies, incidents that have happened at such plants, and also some accidents that have happened overseas involving human exposure.

Radiation Safety

The author of this report was also Chairman of a review of Radiation Safety at the Steritech Gamma Irradiation Facility in Dandenong, Victoria. That Review was conducted on behalf of the Victorian Government. The Review concluded that the plant operates in a safe and satisfactory manner and does not present a significant radiological hazard to either plant operators or members of the public. This report was provided to the House of Representatives Committee.

During the course of the House of Representatives Inquiry the opportunity was taken to investigate the operation and safety of the Ansell-Steritech Plant at Wetherill Park, Sydney, and the Johnson and Johnson Plant at Botany also in Sydney.

Following the visit (19/4/88) to the Johnson and Johnson plant the following notes were prepared.

1. The plant is built to AECL JS6500 series design, and came into operation in 1972. It is used only for the sterilisation of Johnson and Johnson's own products (in practice, mainly tampons).

2. The current loading is about 10 petabecquerel (10PBq) of Cobalt-60, i.e. about 25% of design capacity.

3. The cycle time is 22 minutes. The plant runs automatically, there are no operators in attendance outside normal working hours. However, the control panel is duplicated in the entrance guardhouse which is staffed continuously.

4. The principal plant operator has an AECL training certificate and has also successfully completed the NSW Department of Health's Industrial Radiographers Safety Course.

5. The personal dosimeters (film badges) used are from the NSW Department of Health, with a quoted lower limit of 20 millirem (0.2 millisievert). I reviewed the film results for the past 12 months - all results were less than 0.2 millisievert.

6. The company has 4 RATO-F portable radiation monitors. They are calibrated by ANSTO every three months. The three I inspected (one was away for calibration) were all in working order, with up to date calibration certificates.

7. Some radiation measurements were taken around the plant and obtained the following results:

   a) at the product exit:

      0.01 millisievert per hour with the barrier door shut
      0.07 - 0.08 millisievert per hour with the barrier door open

   b) on the shielding wall directly opposite the source:

      0.005 millisievert per hour at waist height
      0.020 millisievert per hour at head height

   c) general levels around the plant: 0.0001 millisievert per hour (i.e. background radiation level).

   These radiation levels are satisfactory. The film badge results noted in (5) above confirm the low dose rate levels to which plant operators are exposed.

8. The required maintenance procedures are carried out on a monthly basis. The various checks are logged automatically on an electronic recording system. The last check prior to my visit was dated 7/4/88 and appeared correct.

9. Particular enquiries were made concerning the fire that occurred inside the radiation cell area on 14/11/82. This event is discussed in the section on incidents.

10. The overall impression was of a well run plant operating significantly below capacity. The Plant Manager and Principal Operator both had a clear understanding of the nature of the plant, potential hazards and safe operating procedures.

11. It was considered that there is negligible radiation risk to plant personnel during normal operation of the plant.

A visit was made to the Ansell-Steritech Gamma Sterilization Plant at Wetherill Park on 18/4/88. The following observations were made after that visit.

1. The plant is built to AECL specification JS 8900 and it was opened in December 1985 as a commercial irradiation service.

2. The plants design capacity is 80 petabecquerel. The current loading is about 25 petabecquerel.

3. The plant irradiates mainly medical supplies. It could be modified to irradiate foodstuffs but materials handling procedures would have to be changed.

4. At present the plant runs on three shifts, at about 98.4% of the possible maximum operating time. There are two dayshift operators, with one operator on each of the afternoon and night shifts. All the plant operators have AECL competency certificates.

5. The Plant Manager is the designated Radiation Safety Officer. He has attended a radiation safety training course at the Australian School of Nuclear Technology (Lucas Heights).

6. The control panel is interlocked to the Chubb Watching Service. There is a 'deadman' button for single operator control (i.e. an alarm sounds each hour, the operator has to press a button to switch it off - if it is not switched off, Chubb notify the Plant Manager).

7. The Company has three RATO-F portable radiation monitors. They are calibrated at ANSTO. They were in working order and their calibration records were up to date.

8. The personal dosimeters (film badges) used are supplied by the Australian Radiation Laboratory. The reported lower limit is 0.01 millisievert per issue period (usually one month). I reviewed the records for the 8 plant staff who receive dosimeters. During the past 12 months there had only been one recorded dose. That was for 0.01 millisievert. That was not a significant dose.

9. At the request of the local Council a continuously reading ozone monitor has been installed in the plant exhaust system. It alarms at 1 part in 10^7 which is the threshold limit for ozone exposure. The monitor is interlocked with the access door.

10. The plant incident log book was reviewed in some detail. In a typical week (25/3 - 31/3/88) there were 13 entries into the cell. Nine were related to product trials. Of the other 4, 2 were because the cylinder that moves the product failed to contact the limit switch. In such a case the source automatically descends to the bottom of the pool. One was

because the product conveyor missed a carrier due to mechanical touch failure. One was because the source did not come up out of the pool. This was due to a solenoid failure, requiring the solenoid to be dismantled and cleaned. None of the events had any radiological significance and did not involve the operators in any radiation exposure.

Criticisms of Plant Operation

A detailed criticism of the operation of the Ansell Steritech Wetherill Park plant was tendered on behalf of Friends of the Earth by Mr Bob Tait who has a Bachelor of Engineering degree (pp 00127-00129). The plant was reviewed with Mr Tait's criticisms in mind and the following observations on Mr Tait's specific points were prepared.

a) TAIT: There is no power back-up for the plant - a power failure allows the source to return under the force of gravity.

RESPONSE: Even with power available the source descends into the pool under gravity, the rate of descent being determined by the rate at which the air is allowed to exhaust from the pneumatic hoist. The usual time taken is about 25 seconds.

The arrangement is considered to be quite satisfactory as gravity is not a force that can be switched off. Cables can jam with or without a power back-up. Such a back-up would have little, if any, effect on the way such a situation would be handled. If power failed remedial action could not be taken until lighting in the plant room was available. It would be a financial liability to the company, not a radiological hazard.

The Committee may consider that emergency lights be installed in irradiation plants as a general safety measure to enable evacuation in the event of a power failure.

b) TAIT: Small holes have been drilled through the roof to allow restricted manipulations with long handled tools. There is no remote controlled system or equipment to deal with an unshielded source.

RESPONSE: The source is intended to be unshielded during normal operations. If it becomes jammed and if the long handled tools can't manipulate the source back into the pool there would be time to arrange a robot with TV and/or remote arm to manipulate the source within the cell. There would not be any radiological risk to personnel whilst this was being arranged and carried out.

On two occasions the source jammed at the Dandenong plant; each time it was returned to the pool following manipulation of the hoist cable (see section of this report commenting on accidents and incidents).

c) TAIT: There are ineffectual safety arrangements for personnel.

RESPONSE: The arrangement of a geiger counter attached to a key which is used to switch the source control on and off has been misunderstood by Mr Tait. The geiger counter is attached to the key to ensure that people entering the radiation room after the source has been lowered into the pool have a counter with them as part of the entry procedure. It is a back-up check to the installed entrance maze monitor which in turn is interlocked to the entrance door. The key and counter being taken into the irradiation area is also part of the control procedure to prevent the source being raised whilst someone is in the irradiation area but there is also a cable running around the irradiation chamber, which if pulled, switches off the plant.

The chain across the maze is the fourth safety control. (It was actually introduced by Ansell at their Dandenong plant and subsequently adopted by the Canadians). The power supply has to be inactivated to allow the access door to open, the chain supplements this. There would be no reason for anyone to step over the chain.

There is room for improvement in safety training. The Plant Manager has attended a suitable course and the operators have appropriate training from the Canadian representatives when new sources are being installed. This training however relates to plant operation, and the automatic running of the plant. The plant controls are linked with the Chubb Watching Service who monitor the plant operation and require the 'Deadman' switch to be operated every hour.

It is perfectly satisfactory for the action to be 'Ring the Plant Manager' as he (or she) is the appropriate responsible person.

Mr Tait notes that the system is OK only if nothing goes wrong. It should be noted that there are several redundant safety features and the design of the plant is such that even if something does go wrong there is no immediate radiological hazard to plant personnel.

d) TAIT: The ventilation system pollutes the environment.

RESPONSE: At the insistance of the local Council a continuously reading ozone monitor has been placed in the exhaust stack. It is set to alarm at 1 part in 10^7 of ozone. This is the threshold limit value. The alarm is interlocked with the source and if it triggers the source returns to the pool.

The question of mutated bacteria and viruses has been discussed by the Committee and Dr MacPhee has provided advice.

e) TAIT: There are difficulties in achieving an even dose.

RESPONSE: This would obviously be a matter for the relevant Licencing Authority to approve or not approve food irradiation based on any modifications to the plant. The Committee will need to consider recommending appropriate tolerances on doses given. This point is discussed in more detail in the section on dose uniformity.

f) TAIT: 'Spent' Cobalt-60 is a problem.

RESPONSE: 'Spent' in this sense means that a pencil is too low in radiation output to be useful for sterilisation purposes. It is agreed that it is an extremely hazardous source of radiation and will need as much care in transportation back to Canada as do fresh sources.

g) TAIT: Cobalt-60 cannot be "recharged".

RESPONSE: This is incorrect. During the initial manufacture less than 25 % of the initial Cobalt-59 is changed to Cobalt-60, so there is the opportunity to reactivate the sources. Even so they will eventually become a waste disposal problem. Clearly Australia has an international responsibility to ensure that they are stored and disposed of in a safe manner when no longer in use. This would be a matter to take up with the suppliers and the supervising and licensing authority.

h) TAIT: The economic life of the rods is 20 years, whereas the warranty is for 15 years.

RESPONSE: All this means is that the rods will have to be decanted from the source holder and inspected very carefully for signs of corrosion towards the end of the 15 year warranty period. If they are satisfactory, they can be used for another 5 years or so. This is I would suggest, a case of the supplier being appropriately cautious. The pencils are wipe tested every time fresh sources are loaded which is also a check of the containment.

Uniformity of Radiation Fields

Several witnesses (including R. Tait, see e) above) have expressed concern about difficulties that can be experienced in obtaining uniform dose fields and therefore uniform irradiation of any product. The procedures for both calculating and measuring dose patterns has been well developed and at the existing Australian gamma sterilization plants they are as follows:

1. The Cobalt-60 rods are supplied by Atomic Energy of Canada Limited (AECL). That organisation is able to determine the specific activity of each rod produced by knowing a combination of:

   a) The neutron flux in the part of the reactor used for the activation of the Cobalt-59, and

   b) The length of time the rods spent in that neutron flux.

   Other important parameters such as the neutron capture cross-section for Cobalt-59 are known physical quantities.

2. Before any fresh rods are inserted into the irradiator source racks at the operating company's premises, AECL calculate the required position of each (OLD & NEW) rod in the source holding module.
   This is a straightforward computational exercise and is done for two reasons:

   a) To produce a uniform dose field and to determine the strength of that field, and

   b) To obtain maximum useful radiation from the older Cobalt rods.

   Thus the loading of fresh sources can involve a significant re-arrangement of the existing rods.

3. AECL provides the operating company with a list of conveyor timer settings needed to achieve particular doses (for sterilization, 25 kilogray). The timer setting will vary depending on the density of the product being irradiated and to allow for the gradual decay of the Cobalt-60.
   The production of timer settings lists is a non-too-complex mathematical exercise carried out by AECL computational staff who have a wealth of experience in preparing such data.

4. For sterilization procedures doses a little above a certain minimum do not pose problems (except to the operations in terms of 'lost' radiation energy and time). Plant operation therefore can be relatively uncomplicated.

5. For food irradiation:

   a) If doses less than one kilogray are required then, either significantly smaller sources and/or faster conveyor operation are necessary.

   There are no inherent problems in achieving uniform, known and controlled radiation doses.

   b) For doses between one and ten kilogray the same reasoning applies except that obviously larger sources or longer irradiation times can be used.

6. However it should be noted that irradiation of foods requiring the delivery of doses within prescribed limits will require changes to plant operating procedures to ensure correct irradiation.

   If a certain foodstuff of a particular density is to be given a specific dose the conveyor timer will need to be set at a pre-calculated point. This will need to be reset before another food item of a different density, requiring a different exposure level, can be irradiated. This would require the run-out of the first item, irradiation would have to take place on a batch by batch basis, which would slow down the operation of the Plant.

7. In summary:

   a) There are no major difficulties in producing uniform radiation fields of carefully known dose rates.

   b) The half-life of Cobalt-60 is known very accurately and it is a simple mathematical exercise to make allowance for this when calculating irradiation times.

   c) Changes to operational procedures will be necessary if and when food is being irradiated. This should not present any problems as operators already have to change timer settings when materials of differing densities are being gamma sterilized.

Incidents and Accidents

There have been two events at Australian gamma irradiation plants which have been brought to the Committee's attention as evidence of the unsafe nature of such plants.

As part of my work for the Committee I investigated both events in some detail.

An Ansell source jam, which was described by the Company as an 'unusual occurrence' took place at the Dandenong plant (then operated by Tasman Vaccine, a Division of ICI Australia) on 13 August 1980, and an earlier similar event happened in May 1979. The then Production Manager was Mr George West, currently Divisional Manager for the plants present operators, Ansell Steritech. Following a review of the plant and discussion with Mr West I made the following notes:

1. Prior to 1975 cardboard tote (irradiation) boxes were used. These became brittle on repeated irradiation and were awkward to unload. In 1975 Tasman-Vaccine designed a metal frame basket to replace the cardboard boxes. The design worked well until May 1979.

2. In that month a basket gate jammed in the overhead rollers, buckling the gate and jamming the source rack. By repeated manouvering of the source hoist cable and the basket pushers the gate was freed and the source descended into the pool. It took about 30 minutes to free the source.

3. The plant was shut down for a further 8 hours whilst various modifications were carried out, including redesign of the basket gate.

4. At 10.40 pm on August 13 the night shift operator telephoned Mr West with the advice that the plant had shut down but that the source had not returned to the bottom of the pool.

5. On Mr West's arrival at the plant several manoeuvres were tried to move the source rack, including raising and lowering the cable (there was about 6 - 7 inches of movement) using a manual winch which had been clamped onto the cable. This was done in the source hoist room above the irradiation chamber. At about 4.00 am the cable snapped, as a result of friction, and disappeared into the cell. It was not realised at the time that the source had now dropped to the bottom of the pool. The snapping of the cable had given the source rack sufficient momentum to clear the obstruction.

6. On Thursday 14 August at 5.00 am advice was sought from AECL who proposed that they send out an appropriately experienced Engineer and Physicist.

7. At 7.00 am further advice was sought from Canada regarding a possible further option to free the jammed source by slackening the guide cables. AECL advised against this proposal and notified Tasman-Vaccine that a 2 man team had already been arranged and would be in Melbourne by Sunday August 17.

8. Late on Thursday, radiation measurements, by amongst others the State Radiation Safety Section, made it clear that the source was now in the 'safe' position at the bottom of the pool. The cell was entered using standard entry procedures. The source rack was at the bottom of the pool, 17 pencils having spilled out of Module No. 4.

9. The Canadians were advised of the changed situation and arranged instead to send out an installation engineer (Mr Jaeger who now works at Dandenong). He arrived on Sunday 16 August, i.e. within 3 days of the initial source jam.

10. All the cobalt pencils were removed from the rack, inspected and leak tested. The source modules were rebuilt, a new cable fitted and basket modified (again). They have now been replaced by AECL designed standard aluminium tote boxes.

11. The jamming was caused when a basket gate that had become buckled, after falling between two conveyor rollers, caught the tip of the source rack when one of the pushers triggered a shut down.

Comments

a) The incident was caused by a combination of faulty basket/gate design and poor plant maintenance, i.e. sticking conveyor rollers. This latter point is clearly acknowledged in the Company's report and one of the remedial actions taken was to adhere strictly to the preventative maintenance schedules. (Note: My recent inspection of the two Ansell Steritech plants confirmed that maintenance schedules are up to date)

b) At no stage was there any radiological hazard to personnel, either on the plant or to members of the public. This would have remained the case irrespective of how long the shut down occurred.

c) The plant was shut down for 126 hours.

d) The severing of the hoist cable which led to the source dropping to the bottom of the pool was fortuitous and not by design (Note: Mr West's evidence to the Inquiry inferred that the cable was cut deliberately - see transcript last paragraph P 00388 - West"...Eventually we cut the cable and it just went straight down to the bottom of the pool". Mr West continues. "That problem no longer occurs as we now have a source sleeve so that it can be lowered to the bottom of the pool without being impeded", which is correct). The severing of the source hoist cable did, by chance, have the desired effect but this was not realised for some 12 hours.

e) If the snapping of the cable had not released the source the jammed gate would almost certainly have had to be released by remote manipulation from the hoist room using the access holes. How easy this would have been, how long it would have taken, and what radiation exposure the Canadian operators may have received is now impossible to judge.

f) The remedial actions taken, including a source rack sleeve, improved maintenance, and use of a different design of tote box, are such that a repeat of this type of incident is now exceedingly unlikely.

Johnson & Johnson Fire

1. The fire occurred some time during the night of 13/14 November 1982 (i.e. Saturday). It was signalled to the Alexandria Fire Station at 4.36 am Sunday, November 14.

2. The plant was operating normally at 2.00 pm on Saturday, November 13, when the plant crew left. Routine inspections by Security Officers noted "source up" lights indicating that the plant was operating normally at 4.30 pm, 7.10 pm and 9.00 pm on Saturday.

3. At 4.30 am on Sunday 14 November, a Security Officer, on routine patrol heard the fire hydrant pumps operating, he noted that the "source down" light was not flashing. The officer tried resetting the pump, on failing to do so he contacted the duty electrician who noted that the "source down" light was now flashing.

4. The Irradiation Operator was called at 4.40 am. He determined from the control console display that the source was in the pool. The Fire Brigade had arrived but had observed the "entry prohibited" signs and awaited further advice.

5. The Irradiation Operator entered the cell maze using standard procedures but was driven back by smoke.

6. The Chief Radiation Officer of the Health Commission arrived at 5.50 am. He and the Irradiation Operator donned breathing apparatus, entered the maze and determined that there was not a radiation hazard. The Fire Officer directed that the sprinklers be switched off so that the internal condition of the cell could be viewed. This was about 4 hours after the initial alarm.

7. The reconstructed sequence of events leading to the fire appears to have been as follows:

   the initial cause appeared to have been the use of poor quality tape used to tape the cardboard product boxes. The tape came unstuck on one of the boxes being irradiated. The lid popped up and on one of the passes the box jammed before the exit maze;

   an associated cause was due to a 115V relay having been plugged into a 12V shutdown circuit. This relay (K52) did not de-energise when the product line stopped. If it had done so the source would have descended into the pool;

   the source was up for about 14 hours irradiating stationary cardboard boxes. One eventually caught fire from the radiant heat emitted by the Cobalt-60;

   the fire activated a thermal detector (there is no smoke detector) and the sprinkler system came on automatically. This in turn de-energised another relay circuit, the plant shut down and the source descended into the pool.

8. At no stage was there a radiation hazard. All personnel involved, both from the plant, the Fire Brigade and the Health Commission followed the correct operational procedures.

9. Several alterations to both plant operations and maintenance procedures were instituted to prevent a re-occurrence. These include:

   colour coding of the control relays. 115V relays are colour-coded RED, and a visual inspection of the relays is made each month;

   the thermal detector has been repositioned;

   an additional sprinkler head has been fitted directly above the source rack to cool the source;

   the control circuitry has been modified so that in the event of a product box jam and a false electrical safety situation then the Unit will shut down after completing a further cycle (i.e. after 22 minutes on the present cycle time).

Conclusions

The fire did not present a radiation hazard to any personnel at any stage.

The personnel from the various groups involved carried out their procedures in a correct manner.

The modifications made should prevent the reoccurrence of a similar type of fire.

In neither incident was there a risk of radiation exposure of either plant or emergency personnel and in both cases the remedial actions taken should prevent a reoccurrence of similar incidents.

Overseas Acccidents

The literature on radiation accidents is not very extensive and the only complete report that has been obtained is of an accident that occurred in Norway in 1982. This led to the death of a technician following uncontrolled entry into the irradiation cell.

The accident happened at the Institute for Energy Technology, Kjeller in a 2.4PBq Cobalt-60 plant. (The Dandenong plant for example, contains 37PBq).

Extracts from the Norwegian report read as follows:

> "September 2. 0338. Operational alarm went off due to failure of the conveyor system. The duty operator decided to wait until working hours to institute remedial action.

0707-0712. The service technician arrived. At 0719 he switched off the operational alarm which was registered in the Institute reception room. The reception officer phoned the irradiation plant and after a short waiting period received an 'everything's alright' message from the service technician.

0730. The service technician was found sitting on the steps of the plant building clearly ill. He was taken to the reception centre. It was assumed he had had a heart attack and was taken by air ambulance to hospital.

0800. The research leader and operator arrived. They were aware that the service technician had been sent to hospital.

The research leader noted that the source indicator was green indicating that the source was shielded and that the door to the irradiation room was wide open. He proceeded to check the radiation levels inside the door, found them high and concluded that the technician had been highly irradiated.

By 0840 the emergency team had assembled and prepared the following report on the status of the plant:

> 'dose recorder: irradiation continuously on since 2130 the previous day;
>
> source condition indicator: level 04 the whole source above floor level,
>
> radiation monitors in working order.'

The patients film badge was too black to read after processing. What had happened was that a microswitch had failed giving a source shielded signal and releasing the barring of the door lock even though the positional display showed the source in an elevated position.

Comparison of the two signals would have shown the discrepancy. There was not, however, a positive failure signal.

In addition the radiation monitor in the interlock system had been taken out of service for maintenance and the radiation dose/interlock system was out of action.

Thirdly, the technician failed to use a monitor to check the radiation level before entering the irradiation room.

As Liev Bertig, Director of the Norwegian Institute for Radiation Hygiene put in his report - 'The technician arrives at the plant. The alarm is on and the display at the staircase entrance shows green, source shielded. He fetches

his operational key and enters the control room where also the green light - source shielded-springs into the eye. He turns off the alarm and unlocks the door with the prescribed use of controls. It is important to get the plant moving so why bother with monitors. After all, the safety system is failsafe, even 'idiot-proof'.

And that's it!.

Of course such a system should be beyond human error, but even it can never be made completely proof against malevolent intentions.

Because of the different interlocking system and procedures, probably the simplest of which is fixing a radiation monitor to the control key, the review panel was convinced that the Norwegian accident could not happen at Dandenong. That is why when we considered the maximum credible accident we opted for the emergence of a pencil from the irradiation area.

Going into the control room with the source exposed would kill the person who did it; a pencil coming out of the product maze could kill 3 or 4 plant operators and produce unacceptable radiation levels in areas around the plant. Even if far from lethal they would cause much public alarm and concern.

More recently a radioactivity release has occurred at an irradiation facility in the United States. An extract from the preliminary report reads as follows:

The State of Georgia advised Region 11 on June 7 1988, of a leaking WESF Caesium-137 source at Radiation Sterilizer, Inc., (RSI), an agreement State licensee located in Decatur, Georgia. RSI irradiates medical products and empty food containers but not food products.

The RSI facility is made up of 252 Caesium-137 WESF capsules, each containing anywhere from 43,000 to 50,000 curies of Caesium-137 in 1 25-foot deep pool. The WESF capsules are leased to RSI from Westinghouse Electric Corporation. RSI is licensed to possess a total of 12.3 million curies of Caesium-137.

Preliminary investigations indicate that one or more of the WESF source capsules has been determined to be leaking and has been doing so since some time after June 3 1988.

All safety systems at the RSI facility functioned as designed. Concentration levels in the pool have been measured at .04 microcurie per millilitre, which equates to approximately four curies of Caesium-137. Radiation levels six inches from the surface of the pool measure 12 to 17 millirem per hour.

Ten RSI employees have worked in the operations area since June 3, and some clothing and minor skin contaminations has been measured on several of these employees. Blood work analyses are being conducted on all potentially affected persons.

RSI has closed the facility and has taken action to minimize the work force to only those personnel necessary for recovery operations and to minimize personnel traffic in the operations area.

This incident would confirm the need to recommend against the use of caesium as an irradiation source.

Review of Safety Features

In presenting evidence to the Committee I commented upon the various safety features at Australian irradiation plants. Dr D.D. Mathews, Radiation Safety officer at Flinders University and a member of the South Australian Radiation Advisory Council reflected adversely upon my evidence.

Effectively Dr Mathews made two points:

1. all the described features are prone to human facility,

2. the frequency of shut-down could lead to operator complacency and over-riding of the automatic shut-down.

To take these points further:

1. In discussing the proneness to human error Dr Mathews draws lessons from Three Mile island (TMI) and Chernobyl in that the weakest link in all systems is the operator. In drawing this lesson I suggest that Dr Mathews is only partially correct. What has been shown by reactor accidents (and I would include a larger list than Dr Mathews e.g. Windscale, Browns Ferry, SL-I etc) is that operator error can show up fundamental design flaws. For instance at TMI the operators were overloaded with information, ringing alarms and a vital warning light was obscured by a maintenance workers service tag. At Chernobyl all the operating procedures were deliberately over-ridden in an almost incredible way and the unsuspected positive reactivity of that design of reactor led to the explosion.

   What such incidents have shown (and it is important to include non-nuclear disasters such as Flixborough, Seveso, Bhopal etc) is that, apart from the sound basic design of the plant (and irradiation plants around the world have demonstrated the correctness of the design and building procedures) what is required is:

a) simplicity and redundancy in safety equipment and controls, along with regular checking and servicing;

b) thorough operating training and supervision;

c) an effective independent supervisory authority to ensure that a) and b) are being complied with. This requires legislative controls be both implemented and policed.

These three criteria are, I consider, satisfied in the case of all three existing commercial irradiation plants. They should form part of any recommendations that might be made if food irradiation is approved.

2. By being disturbed about the frequency of shut-downs Dr Mathews shows a lack of understanding of irradiation plants.

On shut-down the source is automatically returned to the shielded position at the bottom of the pool.

Nothing is achieved by the operators over-riding the automatic shut down circuit on the pretence that it isn't working. It shuts down because it is working. The control panel indicates what part of the system had caused the shut-down. The shut-down occurs for a variety of relatively minor reasons which have nothing to do with radiation safety but with the mechanical operation of the plant and the need to obtain correct dosage to the materials being irradiated.

Radiation Dose Limits

Several witnesses have suggested to the Committee that working in irradiation plants presents an unacceptably high health risk. This argument is based on two interlocking premises.

i) any exposure to radiation is harmful,

ii) existing exposure limits have been set too high.

1) Radiation protection practices are based on the understanding that any radiation exposure carries with it some risk. That risk has been quantified within certain broad limits, and the aim is to contain the risks within acceptable limits. What is and what is not an acceptable risk can be argued, Some such arguments have been put forward by Mr Tony Webb who is co-author of 'Food Irradiation - who wants it?' and co-ordinator of various groups concerned with the health of radiation workers, and victims of nuclear weapons tests, radiation accidents etc.

2) Mr Webb's main thesis is that radiation levels, as set by the International Commission on Radiological Protection, and adopted by the appropriate National or State Authorities have been set too high. He argues for a 15 fold reduction in dose limits.

3) Without arguing the merits of Mr Webb's case it is not directly relevant to the question of food irradiation, as the dose to workers can be controlled to as low a limit as may be required.

4) The reasons for stating this are:

a) the recorded radiation doses received at Ansell Steritech in Dandenong have never exceeded 400uSv in any one year (i.e. 0.8% of the current dose limit) and these doses were received during source loading operations, not during routine operations. (Note the lower limit of dose recorded by the dosimeters used is 10uSv per month).

b) the only recorded dose at Ansell Steritech Sydney during the past 12 months was 10uSv received by the Plant Manager. The different source loading system used in the AECL 8900 plant (Sydney) reduces substantially the length of time any worker is near the transport flask during loading operations, thus effectively removing the source of exposure.

c) doses received by personnel at Johnson & Johnson, Sydney were all below the limit of detection of the film badges used by that Company (NSW Health Dept. lower limit quoted as 20 mrem/month=200uSv/month).

d) the monitored radiation levels around the plants are, with the exception of some known positions, all about background. The positions of slightly higher than background radiation levels are such that workers would not be in those positions for any length of time, and in the case of the Ansell Steritech Dandenong Plant are fenced off.

e) levels at the perimeter of the plant are indistinguishable from background whether the source is in the exposed position or in the pool.

Another opponent of food irradiation was Dr J Coulter (now Senator Coulter, Australian Democrats) who also argued that irradiation plants present an unacceptable radiation hazard to workers in the plant.

Dr Coulter argued that by adopting South Australian Health Commission guidelines for investigating radiation doses, and current dose limits, the cancer risk to women receiving such radiation doses could be increased by as much as 19%.

Clearly if this is correct it is an unacceptable risk and presents a very strong argument against the use of large radiation sources (it is in fact an even stronger argument against the medical uses of radiation sources such as diagnostic Xray units, but Dr Coulter didn't persue that point).

Dr Coulter based his argument on several pieces of data as follows:

a) the South Australian Health Commission reviews film badge results every 3 months, and a dose at or about the quarter dose limit would be a trigger for investigation (note: Mrs J Fitch in presenting evidence on behalf of the Australian Radiation Protection Society confirmed this information, she is, by chance, Head of the Radiation Safety Section of the South Australian Health Commission).

b) the current dose limit for radiation workers is 50 millisievert per year (mSv/y), thus the S.A. trigger dose is 12.5mSv.

c) the Biological Effects of Ionising Radiation Third Report (BEIR III) gives a risk estimate of between 344 and 1306 cases of cancer produced per million women per 10mSv of radiation.

To take these data a little further, let us use the upper risk quoted by Dr Coulter, i.e. 1306 cases per million women each given 10mSv.

i.e. $1306/10^6/10\text{mSv} = 1.3 \times 10^{-3}$ per 10mSv
$= 1.3 \times 10^{-4}$ per mSv.

If an action or trigger level of 25% of the annual dose limit is used the dose received would be 12.5mSv.

Thus the upper risk to a woman receiving this dose would be $12.5 \times 1.3 \times 10^{-4} = 1.6 \times 10^{-3}$
$= 0.0016$.

The incidence of cancer in Australia is between 0.25 and 0.33 (i.e. between a quarter and a third of all Australians develop some form of cancer of whom about half die from that cancer).

If the lower figure of 0.25 is taken the additional risk from the exposure to radiation would be 0.0016 giving a total risk of:

$$0.2516$$

Thus the percentage increased risk is

$$\frac{0.0016}{0.25} \times 100 = \underline{0.64\%}$$

(Note: <u>if</u> the BEIR figures are correct, <u>and</u> this average dose was received over a 40 year working life the lifetime risk would be increased by 25%, not 19% as Dr Coulter calculated).

This is the risk to an individual, based on conservative upper risk estimates, <u>before action is taken to reduce such doses.</u>

If the trigger level was set at 25% of the monthly derived dose limit (*), the upper risk estimate would be 0.05%.

Dr Coulter's figures are not applicable to the gamma sterilization plants operating in Australia:

a) no doses have exceeded 0.8% of the annual dose limit (which using the BEIR upper estimate for males would give a cancer risk of 0.00006, i.e. an increased risk of 0.012%),

b) to date all workers in such plants have been males, although this could of course change.

Conclusion

Dr Coulter's arguments, as with those of Mr Webb, whether valid or not, are not relevant to discussions about radiation risks to plant operators working in the types of plants currently in operation in Australia.

The Committee can ensure that this situation continues by making appropriate recommendations about:

a) plant design, especially limits on dose rates;
b) personnel monitoring;
c) trigger levels for investigation of film badge results.

(*) The dose limit is based on an annual figure, 50mSv per year. For convenience, derived limits are used, i.e. 1mSV per week, or 4mSv per month. These figures are not included in legislation, but are used as working limits in practical situations. The figure of 4mSv per month corresponds to the normal film badge issue period.

Possible Dose Limit Revisions

One of the principal sources of information on the effects of irradiation are the victims of the atomic bombs dropped on Nagasaki and Hiroshima. The body that makes recommendations on radiation exposure limits is the International Commission on Radiological Protection (ICRP) and its reviews, inter alia, date from the Japanese bombings.

A meeting of the ICRP was held in September 1987. In a post meeting statement the Commission advised that it is presently revising its basic recommendations (ICRP 26, 1977) and anticipates that the revisions will be completed in 1990.

As part of these revisions the Commission regularly examines papers relating to risk and particularly notes a very recently published technical report by the Radiation Effects Research Foundation entitled 'The effects of changes in dosimetry on cancer mortality risk estimates in the atomic bomb survivors'.

This report was recognised as giving a definitive account of the average changes in organ dose estimates from exposure to the atomic bombs in Hiroshima and Nagasaki, and of the resultant increase in estimated risks of cancer induction. Under the new 'DS86' dosimetry this increase in risk is reported as being by a factor of about 1.4 compared with the risks that would have been estimated by the former 'T65D' dosimetry, assuming a reasonable relative biological effectiveness of such neutron exposure as is likely to have occurred in the two cities.

In addition, although not strictly an effect of the new dosimetry, the longer follow-up (to 1985) of the population sample for whom 'DS86' doses are available so far, makes possible a more reliable estimate than previously of a group who were young (less than 10 years) at the time of exposure. This inclusion and other factors cited in the paper raise the risk estimate for the exposed population by a total factor of the order of 2. This change is for a population of all ages, whereas for a worker population of ages 18-65 the change will be smaller. This information alone is therefore not considered sufficient to warrant a change in the dose limits for occupational exposure.

For the general population, the increase in risk indicated by the new data is also not considered to require change in recommended dose limits, following the reduction (in 1985) in the principal limit from 5 to 1 mSv in a year (from sources other than medical and natural background radiation).

Since the risk data are as yet far from conclusive, the Commission will await the result of the comprehensive evaluations of its sources of epidemiological information that are currently being made, before judging the consequences for the revision of its system of dose limitation.

At a meeting of the International Radiation Protection Association held in Sydney in April 1988, the Chairperson of ICRP, Dr D. Beninson noted that the implementation of ALARA kept most exposure doses to small fractions of the dose limit and an urgent downward revision is not necessary. The ALARA concept is that all doses should be kept <u>As Low As Reasonably Achievable</u> and if correctly executed should ensure that radiation workers receive relatively small radiation doses.

Nevertheless the UK National Radiological Protection Board has as 'an interim measure' recommended that the occupational dose limit be reduced from 50 to 15 mSv per year. It further recommends that the public dose limit be reduced to 0.5 mSv per year from any one site.

Any reduction that may occur in existing dose limits would not affect the operation of those irradiation plants currently operating in Australia. The exposure levels are either zero or very small fractions of the present dose limits.

Future plants, if approved should be able to operate with at least the same degree of radiological control.

Induced Radioactivity

One argument advanced before the Committee by some opponents of food irradiation is that the irradiation process could make the foodstuffs themselves radiation active from induced radioactivity (NOTE: all foodstuffs are already slightly radioactive from naturally occurring radioactive materials such as the decay products of uranium, potassium-40 etc).

It is accepted by scientists working in this field that induced radioactivity does not occur, indeed most opponents of food irradiation accept this fact, including such activists as Mr Webb.

However one paper by a Mr Heiman Julius set out to show that the effects observed in the Indian irradiated wheat study were due to a form of induced radioactivity from what are known as metastable isomers.

The point that Julius set out to prove was:

> the production of polyploidal cells in Indian children fed irradiated wheat came from the irradiation they received as a result of absorbing radioactive materials induced in the wheat when it was sterilized by gamma irradiation.

The basis of his argument was that:

> past studies have shown that polyploids can be produced in human cells by irradiation. Therefore the polyploids in the Indian children came from the irradiation of their cells. He considers that the only source of that irradiation is from residual radioactive materials produced in the wheat and subsequently absorbed by the children. Therefore this proves that sterilization by cobalt gamma rays produces residual radioactivity. The sensitivity of human cells to polyploid production is a much more sensitive indicator than any other form of monitor which is why the residual radioactivity has not been previously detected. The residual activity is in the form of metastable isomers which have (until now) been overlooked. His argument failed to cover several points.

1. He did not consider other possible mechanisms for polyploid production.

2. He did not make any estimate of the amount of induced radioactivity necessary to produce effects. From data he quotes the Indian children would have needed to receive a dose of about 2 Gy in a relatively short time (weeks).

This would require ingestion of an enormous amount of radioactive material of the order of at least 40 GBq (i.e. 1 Curie), so the levels of induced activity would have had to be very high indeed.

3. He did not consider the photon fluxes, or the reaction cross-section required to induce those activity levels.

4. He did not attempt to identify those stable nuclei that could be made radioactive as he described. From his own reasoning it needs to be something with a relatively short half life and he could have reasoned back to what it might be if it existed.

5. If such levels of radioactivity were induced in the food, that in turn would be so radioactive that it would have produced high external doses for the people handling it.

6. Again if such levels of radioactivity were induced in food, even higher levels of induced activity would be produced in material already being sterilised (in medical supplies) and they would be very radioactive, so much so that they would give high radiation doses to people handling the sterilised goods. Film badge records at Australian plants show that this is not so.

7. A dose of 2 Gy would produce even more significant changes in lymphocytes etc (see MacPhee).

Other points that Mr Julius would appear not to have understood include:

a) sensitivity of counting procedures

In all the studies that have been made of irradiated food induced radioactivity has never been detected and instrument counting techniques are very sensitive. For example analysis of residual radioactivity at the Atomic Weapons Testing sites at Maralinga involve counting times of tens of thousands of seconds and sensitivities of fractions of a bequerel per gram. Thus any induced radioactivity could be detected easily.

b) sensitivity of instruments versus biological systems

The lower limit for biological monitors (i.e. chromosomal damage) is about 0.1 Gray wheres radiation detectors can readily measure levels of less than 1 microgray per hour.

c) possible production of metastable isomers

Mr Julius quotes one Dr Van Tuschscheerer as stating that isomer production is the only possible nuclear process

below 1 Mev, but he didn't say that it occurs. Mr Julius confuses something being possible (but never having been detected) with it actually having occurred.

d) natural radioactivity

Mr Julius dismisses natural radioactivity by saying he would like to see the evidence. There is substantial evidence in both scientific papers (Health Physics Journal, ARL reports) and books (e.g. Eisenbud - Environmental Radioactivity - third edition - Academic Press - New York 1987)

e) radiation dose rates and radiation (photon) fluxes

Mr Julius attempts to make the point that the Indian study results were not replicated by other workers because they used different radiation regimes, and by so doing used different radiation fluxes which failed to produce metastable isomers. The radiation dose rate is dependent upon the flux (number of photons or rays passing through one square centimetre per limit of time) and the energy of the radiation. The International Food Irradiation Project, which was strongly criticised by Julius, used cobalt-60, therefore the energy was the same, and a similar dose rate of 75,000 rads per hour, therefore the radiation flux was the same. Thus if any metastable isomers were induced in the Indian wheat it would also have been induced in the IFIP study, as the radiation regimes were comparable.

Conclusions

Although irradiation plants use very large radiation sources with the potential for very serious accidents, experience has shown that properly constructed, properly maintained and properly policed plants, can operate in a safe and satisfactory manner. The risk to either workers in the plant or members of the public living nearby is negligable.

In this context, properly policed means that the plant operate subject to comprehensive and specific legislative controls that ensure that operator training, control procedures, safety equipment, radiation monitors etc, are all maintained at a satisfactory high level.

Radiological safety and associated health risk are not by themselves arguments against the use of such plants for either the sterilization of medical and other supplies or the irradiation of food.

F P Robotham

M. Inst. P, M.A.I.P., M.A.R.P.S.
Radiation Safety Adviser

APPENDIX 7

SAFETY CONCERNS AT STERITECH PLANT

During the inquiry a number of concerns were expressed regarding the safety aspects of the irradiation plant operated by Ansell Steritech at Wetherill Park in Sydney. The following comment outline these concerns, as listed by Friends of the Earth, and the responses by the Managing Director of Ansell Steritech and the Committees adviser on Radiological Safety.

a) *There is no power back-up for the plant - Complete reliance is placed on the force of gravity to return the Cobalt 60 source to the shielding pool. Cables can become jammed.*

There is no generator standing by as there is no need for backup. Power would only be required if there were a power failure, which is not frequently. If power does fail the plant shuts down and goes into safety mode.

Even with power available the source descends into the pool under gravity, the rate of descent being determined by the rate at which the air is allowed to exhaust from the pneumatic hoist. The usual time taken is about 25 seconds.

The arrangement is considered to be quite satisfactory as gravity is not a force that can be switched off. Cables can jam with or without a power back-up. Such a back-up would have little, if any, effect on the way such a situation would be handled. If power failed remedial action could not be taken until lighting in the plant room was available. It would be a financial liability to the company, not a radiological hazard.

b) *Small holes have been drilled through the roof to allow restricted manipulations with long handled tools. There is no remote controlled system or equipment to deal with an unshielded source.*

The source is shielded at all times either by water or concrete walls. If for some reason the source rack cannot go back into the pool and is suspended or stuck there are holes where the lead shot can be taken out and long handled tools can be used to try and free it. The chances of that happening are extremely remote. When the rack is in the up position you cannot get into the chamber, the door is electrically locked.

The source is intended to be unshielded during normal operations. If it becomes jammed and if the long handled tools can't manipulate the source back into the pool there would be time to arrange a robot with TV and/or remote arm to manipulate the source within the cell. There would not be any radiological risk to personnel whilst this was being arranged and carried out.

On two occasions the source jammed at the Dandenong plant; each time it was returned to the pool following manipulation of the hoist cable.

c) *To raise the Cobalt 60 from its shielding pool it is necessary to use a key which is attached to a geiger counter. Anyone entering the chamber is supposed to take the key and counter to prevent the raising of the Cobalt 60 by someone who did not know they were inside. However the key and counter could easily be left outside, or the key detached, with lethal misunderstanding.*

The only way to bring the source rack up is by going to the farthest corner of the chamber, inside, and throwing a switch which starts a timing mechanism in the control console. You then have to come out, close the door, hook the chain and throw another switch at the control console. The plant cannot be started up from outside.

The arrangement of a geiger counter attached to a key which is used to switch the source control on and off has been misunderstood. The geiger counter is attached to the key to ensure that people entering the radiation room after the source has been lowered into the pool have a counter with them as part of the entry procedure. It is a back-up check to the installed entrance maze monitor which in turn is interlocked to the entrance door. The key and counter being taken into the irradiation area is also part of the control procedure to prevent the source being raised whilst someone is in the irradiation area but there is also a cable running around the irradiation chamber, which if pulled, switches off the plant.

d) *People gain access to the chamber through a maze with a single chain across at about waist level. When the chain is undone this automatically activates the power supply that lifts the Cobalt 60 out. It would be simple to go over or under the chain, in which case the power supply would not be inactivated.*

The chain does not interrupt the power supply, it interrupts the supply of air to the hoist mechanism. The chain is only one of a number of procedures which have to be encountered before the plant can be started up. It is true that the operator is relied on to unhook the chain. It can be jumped over but that does not mean the source rack is going to come up. There is still need to throw the key, walk out again, go to the console and throw the key there. The human element comes into it but we rely on the operator unhooking the chain.

The chain across the maze is the fourth safety control. It was actually introduced by Ansell at their Dandenong plant and subsequently adopted by the Canadians. The power supply has to be inactivated to allow the access door to open, the chain supplements this. There would be no reason for anyone to step over the chain.

e) *The plant manager has had training on safety but the people who operate the plant have none at all. At times there is only one worker operating the whole system with no supervision or control of what goes through.*

The operator is controlling what is going through the plant as he has to load the product carriers. The system is completely automatic and nobody has to work the plant. When it is started up it just goes. There is nobody pushing buttons, unless something goes wrong, and then it automatically shuts down.

There is room for improvement in safety training. The Plant Manager has attended a suitable course and the operators have appropriate training from the Canadian representatives when new sources are being installed. This training however relates to plant operation and the automatic running of the plant.

f) *The response to almost every emergency alarm is the instruction to ring the Plant Manager. There is no apparant link up with civil or other emergency services. The whole system would be ok if nothing goes wrong.*

The plant controls are linked with the Chubb Watching Service who monitor the plant operation and require the 'Deadman' switch to be operated every hour.

It is perfectly satisfactory for the action to be 'Ring the Plant Manager' as he (or she) is the appropriate responsible person.

It was stated that the system is ok only if nothing goes wrong. It should be noted that there are several redundant safety features and the design of the plant is such that even if something does go wrong there is no immediate radiological hazard to plant personnel.

g) *The Cobalt 60 in the chamber converts air into ozone and if allowed to remain ozone would attack packaging and food, therefore it must be removed. The exhaust system ensures a complete change of air inside the chamber once every minute. However the filter system is crude, composed of a cloth filter to trap particles and a charcoal filter to chemically*

remove some of the ozone. There is no system to remove bacteria and viruses from the air discharge. As food contains large amounts of bacteria and viruses there will be huge quantities of mutated bacteria and viruses discharged into the air surrounding the plant.

At the insistence of the local Council a continuously reading ozone monitor has been placed in the exhaust stack. It is set to alarm at 1 part in 10^7 of ozone. This is the threshold limit value. The alarm is interlocked with the source and if it triggers the source returns to the pool.

The question of mutated bacterial and viruses is addressed in the body of the report. Biological filters are considered unnecessary.

h) *The plant is designed solely to give a minimum radiation dose which is not appropriate for irradiating food. The layout of the plant does not permit rotating the goods so than an even dose can be given.*

The plant is not designed to irradiate food.

i) *After 20 years Cobalt 60 is "spent". This does not mean it is harmless: it can be lethal. Proponents of food irradiation say that Cobalt 60 can be re-charged. This is incorrect. When Cobalt 60 loses its activity it does not revert to Cobalt 59 but to Nickel 60, and is therefore not in a position to be re-activated and becomes problematic nuclear waste.*

'Spent' in this sense means that a pencil is too low in radiation output to be useful for sterilisation purposes. It is agreed that it is an extremely hazardous source of radiation and will need as much care in transportation back to Canada as do fresh sources.

It is not correct to state that pencils cannot be recharged during the initial manufacture as less than 25% of the initial Cobalt-59 is changed to Cobalt 60, so there is the opportunity to reactivate the sources. Even so they will eventually become a waste disposal problem. Clearly Australia has an international responsibility to ensure that they are stored and disposed of in a safe manner when no longer in use. This would be a matter to take up with the suppliers and the supervising and licensing authority.

j) *The economic life of the rods is 20 years, yet the warranty is for only 15 years.*

All this means is that the rods will have to be decanted from the source holder and inspected very carefully for signs of corrosion towards the end of the 15 year warranty period. If they are satisfactory they can be used for another 5 years or so. This is a case of the supplier being appropriately cautious. The pencils are wipe tested every time fresh sources are loaded, which is also a check of the containment.

APPENDIX 8

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

MODEL FOOD STANDARDS REGULATION

S3. IRRADIATION OF FOOD

(Adopted by Council at the Hundred and First Session in June 1986)

(1) For the purpose of this regulation -

(a) 'ionizing radiation' means -

(i) electromagnetic radiations including X-rays and gamma rays;

(ii) particulate radiations including alpha particles, beta particles, electrons, protons and neutrons;

(iii) all other radiations capable of producing ions directly or indirectly in their passage through matter;

(b) 'irradiation' means the processing of food by subjecting it to the action of ionizing radiation.

(2) (a) A person shall not expose food intended for sale or intended for use in the preparation of food for sale to ionizing radiation save as expressly permitted by and in compliance with this regulation.

(b) A person shall not prepare for sale, pack for sale or sell food that has been exposed (either intentionally or unintentionally) to ionizing radiation save as expressly permitted by and in compliance with this regulation.

Provided that it shall not be an offence as defined in this paragraph to so prepare, pack or sell food that has been irradiated at a place outside the State under and in accordance with laws substantially similar to this regulation in force at that place.

(c) This regulation does not apply to ionizing radiation imparted to food by measuring instruments used for the purposes of inspection.

(3) (a) Subject to this regulation, the ionizing radiations specified in this paragraph may be used for the irradiation of food, viz -

(i) gamma rays from the radionuclides cobalt 60 and caesium 137;

(ii) X-rays generated by or from machine sources operated at an energy level not exceeding 5 MeV (Million electron Volts);

(iii) electrons generated by or from machine sources operated at an energy level not exceeding 10 MeV.

(b) Ionizing radiation that -

(i) is of a type other than a type specified; or

(ii) has an energy level exceeding that specified with respect to that type of radiation,

in paragraph (a) of this subregulation shall not be used for the irradiation of food.

(4) (a) Only the following foods may be processed by irradiation -

(i) cereals;
(ii) fruits and dried fruits;
(iii) poultry;
(iv) herbs and spices;
(v) vegetables and dehydrated vegetables.

(b) The overall average dose of ionizing radiation absorbed by a food that has been processed by irradiation shall in no case exceed 10 kGy (kiloGray).

(5) (a) Irradiation of food shall not be carried out otherwise than in an approved facility and -

(i) by or under the direct supervision of a person licensed in that behalf; and

(ii) by means of irradiating apparatus registered for that purpose,

by [the Minister under the relevant State or Territory Radioactive Substances Act].

(b) Without derogating from paragraph (a) of this subregulation -

(i) facilities referred to therein -

(A) shall be designed to meet the requirements of safety, efficacy and good hygienic practices with respect to food processing;

(B) shall be staffed by adequate trained and competent personnel;

(ii) control of the processing of food within the facility shall be carried out in accordance with the [Code of Practice for the Operation of Irradiation Facilities used for the Treatment of Foods based on that of the Codex Alimentarius Commission (CAC/RCP 19-1979 (Rev. 1)) to be developed by the Radiation Health Committee of the National Health and Medical Research Council] and shall include the keeping of adequate appropriate records;

(iii) facilities referred to therein and records shall be open to inspection at all reasonable times by [the Minister, the Director-General or] an authorized officer.

(6) (a) Nothwithstanding this regulation, food shall be processed by irradiation only where such processing fulfills a technological need or is necessary for a purpose associated with food hygiene.

Food shall not be processed by irradiation as a substituted procedure for good manufacturing practices.

(b) The ionizing radiation dose applied for the purpose of irradiating food shall be the minimum that is reasonably commensurate with the technological and public health purposes to be achieved and shall be such as is in accordance with good radiation processing practice.

(c) A person shall not irradiate food for any purpose unless the irradiation of that food for that purpose and the average dose of ionizing radiation to be applied have been approved by the National Health & Medical Research Council and the irradiation is carried out in accordance with the terms and conditions of the approval.

(d) Food to be processed by irradiation and the packages and packing materials used or intended for use in connection with food so processed -

(i) shall be of suitable quality and in an acceptable hygienic condition appropriate for the purpose of such processing;

(ii) shall be handled before and after irradiation according to good manufacturing practices taking into account, in each case, the particular requirements of the technology of the process.

(7) (a) Subject to this subregulation, food processed by irradiation in accordance with this regulation shall not be re-irradiated.

This subregulation does not apply to food with low moisture content (including cereals, pulses, dehydrated food and the like) that has been irradiated for the purpose of controlling insect re-infestation.

(b) For the purposes of this regulation, food shall be taken as not having been re-irradiated where -

(i) food prepared from materials that have been irradiated at low dose levels (not exceeding in any case 1 kGy) is irradiated for another technological purpose;

(ii) food containing less than 5 per centum of irradiated ingredients is irradiated;

(iii) the required full dose of ionizing radiation is applied to the food in divided doses for a specific technological reason.

(c) Notwithstanding this subregulation, the cumulative overall average dose of ionizing radiation absorbed by a food shall not exceed that specified in subregulation (4).

(8) (a) Records required to be kept in compliance with subregulation (5) of this regulation shall include particulars as to -

(i) the nature and quantity of the food treated;
(ii) lot identification;
(iii) the process used and compliance therewith;
(iv) the overall average dose absorbed by the food;
(v) an indication whether or not the product has been irradiated previously and if so, details of such treatment;
(vi) date of irradiation.

(b) Records pursuant to paragraph (a) of this subregulation shall be kept for a period of time that exceeds the shelf life of the irradiated food product in question by 1 year.

(9) (a) There shall be written in the label on or attached to a package containing food that has been processed by ionizing radiation, in standard type of 3 mm, the words -

"TREATED WITH IONIZING RADIATION"

or

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

(b) When an irradiated product is used as an ingredient in another food, this shall be so declared in the list of ingredients.

(c) When a single ingredient product is prepared from a raw material which has been irradiated, the label of the product shall contain a statement indicating the treatment.

(10) A person who consigns irradiated food shall ensure that shipping documents accompanying or referring to that food include information that the food has been irradiated, the average dose, the identity of the facility where the food was irradiated, the date or dates of irradiation and the identification of the lot or lots of irradiated food in the consignment.