Appendix 2: Issues raised in submissions and FSANZ response

The following table contains detailed responses to issues raised by submitters, in response to FSANZ's call for submissions. A high level summary of the main issues and FSANZ's responses is provided at Table 3 of the Approval Report.

No.	Issue	Raised by	FSANZ response
	Lack of scientific rigour		
1	Submitters made a range of comments regarding a lack of scientific rigour in FSANZ's assessment of the application, the quality and amount of scientific evidence, and FSANZ's scientific credibility, including: - The application is no basis for wide-ranging changes to food regulations covering irradiation. - The scientific substantiation in FSANZ's assessment is unsatisfactory, as it is based on minimal evidence and overgeneralises the potential impact of expanding the number of permitted irradiated foods on nutrition and public health. - The nutritional and safety assessment relies on unpublished non-peer reviewed research submitted by the applicant. - There are gaping holes in data that are needed to prove the treatment safe. - Research should be conducted into concerns related to side-effects and food quality, without kickbacks. - FSANZ makes the fundamental error of asserting that lack of evidence of harm is the same as evidence of safety.	Food Irradiation Watch/Gene Ethics Wiser Equity Pty Ltd Private individuals	The safety and wholesomeness of irradiated foods have been the subject of considerable research, which has been reviewed and evaluated by joint expert committees of the International Atomic Energy Agency (IAEA), the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations. These organizations, along with the Codex Alimentarius Commission (CAC) and a number of regulatory agencies have endorsed the safety of food irradiation, providing that Good Manufacturing Practices (GMPs) and Good Irradiation Practices (GIPs) are used. FSANZ's risk assessments are undertaken in accordance with the most up-to-date international risk assessment procedures and using the best available scientific evidence. FSANZ has previously assessed and characterised the risk from consumption of irradiated fruit and vegetables, as part of its assessment of applications submitted to the agency since 2002 (see Supporting Document 1 (SD1)). Collectively, these risk assessments considered all of the relevant information that was available at the time (national and international), including animal toxicity and nutrition data relating to the safety and nutritional adequacy of irradiated foods. In addition, FSANZ undertook a dedicated review on the nutritional impact of irradiation of fruit and vegetables, published as a review in 2014. For this application, FSANZ conducted a comprehensive review of the scientific literature that has been published subsequent to the earlier risk assessments and the 2014 review of the literature. The weight of evidence indicates that there are no new public health or safety concerns that need to be addressed as part of the current application. As part of their application, the applicant was required to provide FSANZ with evidence that supports the safety and nutritional adequacy of irradiated produce. Whilst this information is useful, FSANZ did not rely solely on the information submitted by the applicant, but conducted its own comprehensive assessment of the scientific literature.

No.	Issue	Raised by	FSANZ response
2	Submitter considers that the evidence base provided by the applicant was flawed or inadequate, specifically: 1. The application fails the test for levels of evidence required. Level 5 peer-reviewed publications are essential. 2. The Executive Summary does not provide a list of references, this is not enough for a proper analysis. 3. The use of a 'personal communication' from a business that stands to gain from the proposal is not appropriate. 4. Selective use of data: 'Available data' does not prove adequate investigation of data, but appears to be an excuse for failure to investigate fully. In particular it fails to give due attention to alternatives to irradiation.	Private individual	1. FSANZ is unaware of 'Level 5 peer-reviewed publications' and queries whether the submitter is referring to the 5 levels of evidence. Level 5 typically refers to evidence of lower quality (e.g. case reports or expert opinion) and therefore FSANZ queries why the submitter would suggest Level 5 evidence as being essential. 2. A list of references was provided in the application (located directly before the appendices), available on the FSANZ website here: https://www.foodstandards.gov.au/code/applications/Pages/A1193.aspx 3. The application has made one reference to 'personal communication' and this is in relation to a statement made by an individual from the FAO/IAEA Joint Division that several countries have approved irradiation for fruit and vegetables as a class, but are not thought to be seriously considering phytosanitary treatments at present. FSANZ is of the view that this statement is simply a description of the current status of the approval/use of phytosanitary irradiation in other countries, as understood by that individual and, in that context, is appropriate for inclusion. 4. Subsection 18(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) requires that in developing or reviewing food regulatory measures, the Authority must have regard to the need for standards to be based on risk analysis using the best available scientific evidence. FSANZ's approach to risk analysis is based on the Codex risk analysis framework. With regards to alternative treatments, if permission to use irradiation is granted, it will be an additional tool that can be used as a phytosanitary measure to treat pests such as fruit fly. FSANZ has been advised by quarantine authorities that irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests and would provide an effective alternative to currently used disinfestation methods. Industry has advised FSANZ that while other options exist, these may be unsuitable for use in certain circumstances due to potential phytotoxicity and quality issues. In such circumstances industry considers that irradiation is a feasible alternative. No credible evidence to the contrary was provided by submitters or located by FSANZ.
	Safety assessment		
3	**General support** A submitter noted that irradiation has been researched and proven safe and efficacious since the early 1900s; its use as a pest disinfestation treatment has been endorsed by the World Health Organization (WHO), US Food and Drug Administration (FDA),	Melissa's World Variety Produce, US Steritech, Queensland	Noted.

No.	Issue	Raised by	FSANZ response
	Centers for Disease Control and Prevention (CDC), and the US Department of Agriculture (USDA). Another submitter noted that the lack of dangerous chemicals ensures the safety of consumers and employees at treatment facilities.		
4	**General safety issues** The submitter referenced the following articles regarding the health impacts of food irradiation: 1. The dangers of food irradiation – Dr Gayle Eversole PhD, ND[1]. 2. Food irradiation, threat to our health or an ideal alternative to chemical/heat treatment?[2]. 3. Food irradiation – unresolved issues – David Acheson, Donald B. Louria[3].	Private individual	1. FSANZ notes that the article by Gayle Eversole is supportive of food irradiation. 2. The SuppVersity blog is generally supportive of irradiation and expresses the opinion that irradiation is safe and will have less effect on food than foods processed using other techniques. 3. The concerns raised in the Acheson and Louria opinion are based on two studies, one in India and one in China. The study in India was that of Bhaskaram and Sadasivan who reported chromosomal aberrations in malnourished children fed irradiated wheat. The study lacked statistical power, and attempts to replicate the results in experimental animals (George et al. 1976)[4] and in humans have not been successful (Truswell 1987)[5]. Malnutrition has been shown to cause a significant increase in the frequency of chromosomal abnormalities in children (Armendares et al. 1971[6]; Mutchinick et al. 1979[7]). It is therefore unlikely that the chromosomal defects in the children were due to the wheat, and most likely that they reflected malnutrition. The study in China was that of the Shanghai Institute of Radiation Medicine (1987) and concluded that there were no effects on chromosomes of healthy young adults consuming irradiated food for three months. Acheson and Louria re-examined the data and concluded that the subjects did have chromosomal breaks at 'borderline statistical significance', but acknowledged that the results are inconclusive. FSANZ notes that other studies in animals and human beings have found no evidence of chromosomal aberrations, and concludes that the weight of evidence does not support the hypothesis that consuming irradiated foods causes chromosomal damage.

[1] https://rense.com/general81/foodr.htm (1998).
[2] https://suppversity.blogspot.com/2017/05/food-irradiation-threat-to-our-health.html.
[3] https://academic.oup.com/cid/article/33/3/378/278056 (2001).
[4] George et al. (1976) Frequency of polyploidy cells in the bone marrow of rats fed irradiated wheat. Food and Cosmetics Toxicology 14: 289-291.
[5] Truswell (1987) Food Irradiation British Medical Journal 294(6585) 1437-1438.
[6] Armendares et al. (1971) Chromosome abnormalities in severe protein calorie malnutrition. Nature 232: 271-273.
[7] Mutchinick et al. (1979) Frequency of sister chromatid exchanges in severe protein calorie malnutrition. Annales du Genetique 22(3): 129-132.

No.	Issue	Raised by	FSANZ response
5	Specific concerns raised by submitters about the safety of irradiated produce included: 1. whether safety of irradiated produce is based on evidence from peer-reviewed studies in reputable journals. 2. whether long-term studies have been conducted on human consumption of irradiated foods. 3. that irradiated food would be radioactive, drawing comparisons to X-rays being harmful to humans in large doses. 4. concerns that pectinesterase enzyme (PE) activity especially in citrus, and the possibility of inhibiting phenylalanine in fruits and vegetables. The submitter expressed concern that this would alter protein metabolism in humans. 5. There is no evidence provided that irradiation is safer than existing heat treatment methods or that the risks arising from the lack of irradiation will protect humans or animals from contaminants toxins or disease-causing organisms in foods, beverages or feedstuffs; or prevent the establishment or spread of pests. 6. the submitters urged FSANZ to undertake 90-day ingestion studies, ethically approved.	Private individuals GE Free Northland Health practitioners Academia Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ Food Irradiation Watch/Gene Ethics	1. Safety of irradiated produce is based on extensive evidence from peer-reviewed studies in reputable journals. The by-products of irradiation of food are well-characterised and hazard assessments of those by-products have been conducted by the WHO, the European Food Safety Authority (EFSA), the US Food and Drug Administration (US FDA), FSANZ, and other regulatory agencies. Submitters are referred to the references cited by the WHO (1981, 1988, 1994, 1999), the EFSA (2011a, b) and by FSANZ in this and previous assessments (see Table 1 of SD1). Full reference details are available in the References section of SD1. FSANZ has reviewed and cited extensive scientific research on this topic. 2. Phytosanitary irradiation has been in commercial use since 1986, and has been in continuous commercial use since 1995. This represents a long history of safe use in the general population. In addition, diets composed entirely of irradiated food have been consumed for protracted periods by astronauts and by patients with severe immunodeficiencies. Three-generation safety studies of irradiated foods in animals show that there are no adverse effects in F1 and F2 generations, and this is consistent with studies showing that consumption of irradiated food does not have effects on genetic material. Furthermore, there are a number of rodent models of immunodeficiency disorders (e.g. athymic nude mice) that have been bred for many generations while requiring irradiated foods at all times. 3. The submitter should note that irradiated food is not radioactive. 4. Fruit and vegetables are not major dietary sources of phenylalanine. The major sources of dietary phenylalanine are dairy products, meat, fish, eggs, nuts, and soybeans. Therefore inhibition of phenylalanine in fruit and vegetables will not have a significant effect on protein metabolism. 5. The application does not seek approval for irradiation to protect consumers from contaminants, toxins or pathogens, but to prevent the spread of pests such as the Queensland fruit fly. Phytosanitary irradiation has a satisfactory history of success for this purpose. 6. The existing database on safety of irradiated food includes 90-day dietary studies and much longer studies. There is no indication for further 90-day studies.
6	Specific studies or articles cited by submitters suggest that food irradiation is unsafe, on the basis of alleged toxic effects.	Private individuals GE Free Northland Health practitioners Academia	The cited studies cover a large number of concerns and questions related to the safety of food irradiation. FSANZ has reviewed all the studies provided. In summary, FSANZ finds that most of the studies or articles have either been addressed in previous FSANZ risk assessments, or are incorrect, not relevant to the current application, have been misrepresented in the article, or actually support irradiation. Specific responses are provided in Attachment 2.1, organised as follows:

No.	Issue	Raised by	FSANZ response
		Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ Food Irradiation Watch/Gene Ethics Organic Industries of Australia	2.1 (a) Studies cited in the article 'Bad Taste: The Disturbing Truth About the World Health Organization's Endorsement of Food Irradiation'. 2.1 (b) Studies cited in a 2003 review 'Questioning Food Irradiation: A History of Research into the Safety of Irradiated Foods', Public Citizen, Critical Mass Energy and Environment Program Washington D.C. April 2003. 2.1 (c) Studies that the submitter suggested should be included in FSANZ's safety assessment (Organic Industries of Australia). 2.1 (d) Studies related to formation of radiolytic compounds, free radicals, carcinogens, and other toxic chemicals.
7	Submitter considers that the Codex revised standard on irradiated food (2003) does not support A1193 because it predates cases of serious toxic effects from the consumption of irradiated foods which remain poorly understood.	Food Irradiation Watch/Gene Ethics	FSANZ is unaware of the emergence since 2003 of any serious toxic effects from the consumption of irradiated foods by humans. See response to no. 20 (under 'Adverse effects in cats') for FSANZ response on the effects on cats.
8	**Quantum leap in public health and nutritional risk** Despite FSANZ's low estimates of the amount of irradiated foods that will be marketed, the proposed permissions could result in a quantum leap in public health and nutritional risks, given the high levels of intake of fresh fruits and vegetables among large sections of our population, which will see a significant increase in the amount of irradiated food in the community's diet. This is of concern because numerous studies have shown the potential health risks and hazards that irradiated foods pose.	Food Irradiation Watch/Gene Ethics Wiser Equity Pty Ltd	There is no robust evidence that there are any potential health risks or hazards from consumption of fruit or vegetables that have been subject to phytosanitary irradiation. Please see the hazard assessment in SD1. The available evidence is that permitting irradiation of fresh fruit and vegetables for phytosanitary purposes will not result in a significant increase in the amount of irradiated food in the community's diet (conservative estimates indicate that between 0.3 – 8% of fresh fruit and vegetables in Australia and New Zealand might be irradiated). No evidence was provided by submitters to the contrary. Wholesomeness of irradiated foods has been the subject of considerable research, which has been reviewed and evaluated by joint expert committees of the IAEA, the WHO and the FAO of the United Nations. These expert groups have uniformly concluded that the food irradiation process does not present any enhanced toxicological, microbiological, or nutritional hazard beyond those brought about by conventional food processing techniques. These organizations, along with the CAC and a number of regulatory agencies, have endorsed the safety of food irradiation, providing that GMPs and GIPs are used.
9	**Widespread safety issue** Irradiation could adversely affect the safety of significant core components of the Australian and New Zealand food supply.	Food Irradiation Watch/Gene Ethics	See response to no. 8 above.
10	**Radioactive food**	Private individual	Yes, the statement is fully supported by the available evidence.

No.	Issue	Raised by	FSANZ response
	Has the statement on the FSANZ website 'Irradiation does not make food radioactive and you can't get sick from eating it – it is as safe and healthy as non-irradiated food' been verified and have studies been undertaken to ensure that there are no longer term issues.		Food irradiation cannot make food radioactive. Ionising radiation passes through the food as gamma rays, X-rays or electron beams. The food does not come in contact with any radioactive sources[8]. Studies in animal models, including multigenerational studies, have shown that there are no long term issues. Furthermore, phytosanitary irradiation has a long history of safe use in the human food supply. Phytosanitary irradiation has been in commercial use since 1986, and has been in continuous commercial use since 1995. This represents a long history of safe use in the general population. In addition, diets composed entirely of irradiated food have been consumed for protracted periods by astronauts and by patients with severe immunodeficiencies. Please see the references cited by the WHO (1981, 1988, 1994, 1999), EFSA (2011a, b) and by FSANZ in this and previous assessments (see Table 1 of SD 1). Full reference details are available in the References section of SD1. FSANZ has reviewed and cited extensive scientific research on this topic.
11	**Untested foods and lack of data on cumulative impact** FSANZ claims that the impact of irradiation on the Australian and New Zealand diet will be either non-existent, insignificant or compensated for from other parts of each person's food intake. But a blanket approval will permit the irradiation of untested fruits and vegetables into the food supply. The sensitivity and impacts are unknown. Scrutiny, auditing and reporting are lacking. There is little hard data from experiments or trials. The cumulative impact thus cannot be ascertained. A significant impact on health thus cannot be ruled out. It is unreasonable to presume that all fresh fruits and vegetables will react in the same way to irradiation. Each of their differing organic structures and compounds indicate the probability of differing reactions. Even if the scientific substantiation of the applicant were of an acceptable level, applying it to all fruits and vegetables as if there was no difference	Food Irradiation Watch/Gene Ethics Private individuals Wiser Equity Pty Ltd Friends of the Earth NZ	There is extensive evidence from experiments and trials that fruit and vegetables that have been subject to phytosanitary irradiation are safe to consume. Health of animals on wholly irradiated diets has been extensively studied. Phytosanitary irradiation has been in commercial use since 1986, and has been in continuous commercial use since 1995. This represents a long history of safe use in the general population. In addition, diets composed entirely of irradiated food have been consumed for protracted periods by astronauts and by patients with severe immunodeficiencies. Please see the references cited by the WHO (1981, 1988, 1994, 1999), EFSA (2011a, b) and by FSANZ in this and previous assessments (see Table 1 of SD1). Full reference details are available in the References section of SD1. FSANZ has reviewed and cited extensive scientific research on this topic. The food matrix affects the sensitivity of vitamins to irradiation, with greater losses observed in pure solution compared to losses of vitamins that are part of a food matrix (WHO 1994). Therefore when assessing the effect of irradiation on vitamin content in food FSANZ considered all of the available data from all categories of fruit and vegetables as defined by the national nutrition survey. No fruit or vegetables were excluded from the nutrition assessment based on their likelihood of irradiation. FSANZ included these data and other information as

[8] https://www.health.govt.nz/your-health/healthy-living/environmental-health/food-irradiation; https://www.epa.gov/radtown/food-irradiation; https://www.fda.gov/food/buy-store-serve-safe-food/food-irradiation-what-you-need-know.

No.	Issue	Raised by	FSANZ response
	between them would be haphazard at best and negligently harmful at worst. Having no safe consumption data for each food to be affected by the application is unacceptable, speculative, and puts public health at risk in exchange for unproven commercial expectations. The application notes that some commodities which are classified as fresh fruits and vegetables, such as avocado, bananas, pineapples and root vegetables including potatoes 'are not likely to be, or would rarely be, irradiated under the requested permission'. The impact and effects of irradiation on these foods has not been included or examined in A1193. The cumulative effect of consumption has not been studied.		outlined in the dietary intake assessment in SD1 to assist in determining the overall impact on nutrient intakes should the application be approved (Section 5.2.6 of SD1).
12	**Food irradiation plus background levels** Although the WHO (1996) report indicated irradiated foods are safe for humans, the studies do not look at multiple layers of additional daily non-ionising radiation exposure (WiFi tec, 5G + microwaving foods, etc.) and low-level exposure over many years. The WHO report was written in 1996, since then there have been many studies on health effects from food-irradiation. The submitter included the following link: https://www.centerforfoodsafety.org/issues/1039/food-irradiation	Private individual	Irradiated food is not radioactive and therefore does not contribute to total radiation dose. There have been very few new studies on food irradiation since the WHO (1996) report and those more recent studies have been reviewed by FSANZ as part of consideration of this application or other applications since the WHO report was published. No evidence that would contradict the WHO report has been identified by FSANZ. The report by the Center for Food Safety is not a peer-reviewed publication and contains a number of incorrect statements. The changes in colour, odour and texture are almost entirely in animal products, not fruit or vegetables, and the only changes reported in vegetables were at a higher dose than that sought in this application. The alleged adverse effects of irradiation refer to very old studies that have been shown to be not repeatable.
13	**Safety for sub-groups** Certain sub-groups of the population i.e. those that make highly selective food choices for cultural, religious, dietary, or lifestyle reasons (e.g. vegetarians and vegans) may be especially affected, however little research has been done on the potential health and other impacts on such groups. It was also stated that children on the spectrum will be affected if this application is approved, and that adding chemicals and toxins to their system is catastrophic and detrimental to their health and wellbeing. There are no studies to prove safe consumption	Food Irradiation Watch/Gene Ethics Private individuals Sustainable Agriculture and Communities Alliance (SACA), Victoria	The dietary intake assessment considers the Australian and New Zealand populations, which takes into account subpopulations, including children with varied eating habits including very high intakes of fruit and vegetables. Irradiated foods have a long history of safe use by the general population and there is no evidence of harm associated with consumption of irradiated foods. Food irradiation has an established history of safe use in immunosuppressed people, and is also used for the diets of astronauts. Phytosanitary irradiation is for control of insect pests such as fruit flies rather than for control of microorganisms.

No.	Issue	Raised by	FSANZ response
	levels for babies and children, who might eat large quantities of fresh fruit and vegetables, compared to adults, and who would therefore receive a higher dose for weight impact from irradiated food toxins. This could impact a young person's health and development leading to negative outcomes for children. Irradiated foods might be useful for severely immunocompromised people, particularly those with delayed-type immunity or acute neutropenia. Only after determination of microbe specific effectiveness should expansion to whole subpopulations with potential immunosuppression (e.g. older people) be considered.		Permitting irradiation of fresh fruit and vegetables for phytosanitary purposes will not result in all fruit and vegetables being irradiated, and mandatory labelling means that consumers have the choice to not purchase irradiated fruits and vegetables. See also responses to no. 10 and no. 11 above.
14	**International** Submitters question the safety of irradiated foods in light of international practices and approvals. Specific comments: 1. In 2003, concerns over the safety of irradiated food led the EU to rule out further irradiation approvals. The EU has maintained its position with no further general approvals. 2. The Australian Senate followed suit with a call for approvals to be halted until further research has been conducted. 3. Submitter is of the understanding that the practice was banned in Australia. 4. There is considerable debate about the health concerns from irradiated food among international agencies and between different countries.	Food Irradiation Watch/Gene Ethics Private individuals Ceres Fresh Foods Wiser Equity Pty Ltd	1. Annual reports from the European Commission to the European Parliament and the Council show that a wide range of foods are irradiated in some 25 facilities in the EU. FSANZ notes that EFSA concluded in 2011 that 'there is no immediate cause for concern' related to consumption of irradiated foods. 2. Food Ministers have approved the irradiation of a variety of foods in Australia in response to Applications A1038 (2011), A1069 (2013), A1092 (2014) and A1115 (2016) since the Australian Senate's statement in 2003. 3. The practice of phytosanitary irradiation is not banned in Australia. Please see Table 1 in SD1 for a list of applications that have been approved in Australia. Please refer to Section 2 of SD1 for an explanation of the technological need. 4. More than 60 countries have approved food irradiation. See Appendix 1 of this report. FSANZ has not found any evidence of 'considerable debate' between regulatory agencies or countries but rather, widespread international consensus on the safety and efficacy of phytosanitary irradiation.
15	**Cannot presume safety due to lack of consumption data** Safety and efficacy cannot be 'presumed', with 'no consumption data available'. But the amounts sold into the retail trade are known approximately. As the foods have been retailed for several years in a few thousand retail outlets (Eustace & Bruhn 2006), it may	Food Irradiation Watch/Gene Ethics Private individual	FSANZ notes on its website that irradiation has been used to keep foods safe since the late 1950s, hence has a long history of use. Some subpopulations such as astronauts and people with severe immunodeficiency disorders have consumed entirely irradiated diets for prolonged periods with no adverse effects. In animals, there have been multigenerational studies, and some laboratory animals such as rodent models of severe combined immunodeficiency have been kept on entirely irradiated diets for many generations.

No.	Issue	Raised by	FSANZ response
	be presumed that retailers are actually selling most of the product. There is no basis for a reliable or honest scientific statement on long term safe human consumption of irradiated foods.		Food irradiation has been approved in more than 60 countries. The first application seeking permission to irradiate food for a phytosanitary purpose in Australia and New Zealand was assessed in 2002. Four more applications were assessed in the 15 years that followed. This shows that the populations have been consuming irradiated foods for almost 20 years with no evidence of adverse effects. The Codex General Standard for Irradiated Foods (CXS 106-1983, Rev.1–2003) dates back to 1983, therefore populations globally have been consuming irradiated foods for over 35 years.
16	**Furan** A dietary exposure assessment of furans would be helpful to show that irradiation of food has no impact on the exposure to furans. The risk assessment could include New Zealand and Australian data from the New Zealand Furan Exposure Assessment (2017) which was part of the 2012-2017 New Zealand Dietary Furan Programme. (https://www.mpi.govt.nz/dmsdocument/41223-2012-2017-New-Zealand-Dietary-Furan-Programme).	New Zealand Food Safety	A review of the data from the New Zealand Dietary Furan Programme was undertaken and a summary of relevant concentration data and estimates of furan dietary exposure has been included in SD1 (Section 3.2.2.1). In addition, consideration of the potential worst case dietary exposure to furan from irradiated fruit and vegetables was estimated and a comparison made with total dietary exposure to furan. This showed that furan from irradiated fruit and vegetables is likely to be negligible in the context of total dietary exposure.
17	**Toxic load** Some submitters were concerned that irradiating fresh produce will create an added toxic load to the body through the average Australian diet, in addition to the herbicides to which conventionally treated produce are exposed. There is no way to regulate this load on a person when treated fruits and vegetables are encouraged to be eaten in large doses by all health officials. It will compound the existing problem of chronic disease and obesity attributed to foods that are processed and low in nutritional value and environmental toxins including herbicides. There must be reasons for the development of major cancers, Parkinson's disease and so on. Research indicates they can be the result of accumulated toxins leading to health challenges. Any process which undermines the natural contents of food is essentially detrimental. Population health is struggling from many chemical assaults. Irradiation will add to the pressures on the health system.	Private individuals	In Australia, the use of agricultural chemicals is regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). FSANZ periodically analyses dietary exposure of the general population to chemicals of public health concern, including herbicides, through the Australian Total Diet Study. These studies have found that levels of exposure via the diet are safe. Only a small proportion of fruit and vegetables would be irradiated (conservative estimates being between 0.3 – 8%). There is no credible evidence that phytosanitary irradiation increases the risk of cancer or Parkinson's disease, both of which are strongly linked to advanced age. There is no credible evidence that phytosanitary irradiation is likely to add any pressure to the health system. The wholesomeness of irradiated foods has been the subject of considerable international research, which has been reviewed and evaluated by joint expert committees of the IAEA, the WHO, and the FAO of the United Nations. These expert groups have uniformly concluded that the food irradiation process does not present any enhanced toxicological, microbiological, or nutritional hazard

No.	Issue	Raised by	FSANZ response
			beyond those brought about by conventional food processing techniques.
18	**Diseases and disorders** 1. Eating irradiated food has been linked to immune system disorders, an increase in abnormal lymph cells, decreased fertility, kidney damage and genetic damage. 2. The effect of the daily consumption of irradiated produce on the gut microbiome and thus the health of humans is unknown. It is important to acknowledge the link that gut health has to mental and physical health for humans, so although an immediately tangible adverse effect is not usually seen, how can FSANZ confidently say that in the long term there may not be any impact in areas such as cancers, digestive disorders, mental health, and organ functionality.	Private individuals	1. Eating irradiated food has not been linked to any of the abnormalities listed in credible, repeatable studies. There is no evidence from lifetime animal studies, or from humans who consumed wholly irradiated diets for prolonged periods (e.g. astronauts, patients with severe immunodeficiency disorders), that phytosanitary irradiation has any effect on risk of cancer, digestive disorders, mental health or function of any organs or tissues. 2. There is no evidence to suggest that consumption of irradiated produce would significantly alter the microbiome in the intestines.
19	**Cancer and mutagenic effects** 1. The population is faced with irradiation from many sources apart from natural radiation. Accumulated data from World War II onwards indicates that any type of radiation accumulates and is retained in the body, having mutagenic effects, and there is no real safe level of radioactivity. Radiation has been linked to cancers for decades. Susceptibility to radiation varies, therefore some individuals are more likely to succumb to cancers as an effect of radiation. 2. One study found that an irradiated diet produced abnormal cells, but it was disregarded when critics found that the sample size of cells were too small. Another test-tube study showed that irradiation caused changes in chromosomes and was toxic to cells, but was also disregarded when scientists could not rule out other causes. 3. Irradiation causes toxins that can cause cancer. 4. Studies have been conducted that show food that has been irradiated and fed to animals provoked genome instability raising serious concerns regarding oncogenic potential of irradiated consumables – concern is that the risk of cancer	Private individuals	1. Irradiated food is not radioactive and does not represent a source of human exposure to ionising radiation. Numerous long-term studies of irradiated diets in experimental animals, as well as a long history of use of irradiated foods in human populations, show that risk of cancer does not increase as a result of consumption of fruits or vegetables subject to phytosanitary irradiation. 2. The submitter who refers to abnormal cells and chromosomal damage did not provide details of the studies to which they refer. FSANZ has not found any evidence from properly conducted, repeatable studies that food irradiation causes abnormal cells, chromosomal damage, or genomic instability. 3. Hazard assessment of the radiolytic products is included in SD1. It was concluded in this and previous FSANZ hazard assessments of radiolytic products, as well as by the WHO, EFSA, US FDA and other regulatory authorities, that phytosanitary irradiation does not increase the risk of cancer. 4. The submitter provided a link to an article in an open access online journal. The finding concerning genome instability was in an *in vitro* study conducted by exposing cultured human lymphocytes to irradiated sucrose, not from food fed to animals. The findings have not been repeated in well conducted, repeatable studies in animals and are not considered relevant to the current

No.	Issue	Raised by	FSANZ response
	will increase.		application. FSANZ notes that some animal models of immunodeficiency, such as athymic nude mice, have been fed wholly irradiated diets for many generations without exhibiting genomic instability.
20	**Adverse effects in cats** Submitters are concerned about the health impacts of irradiation as related to the reported adverse neurological impacts on cats with the following points: • Despite the identified risks, Australian regulators have previously allowed cat food irradiation as a quarantine measure[9]. • That FSANZ has belatedly acknowledged the feline pathogenic model for toxigenicity related to consumption of irradiated food despite providing no insight into the exact mechanisms involved in this toxic effect. To arrive at the conclusion that these effects are indeed cat-specific, other animal models would need to have been tested. • That in 2009 irradiation of cat food was banned in Australia but this information was left out/censored from Application A1193.	Private individuals Food Irradiation Watch/Gene Ethics Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ Wiser Equity Pty Ltd Friends of the Earth NZ	FSANZ does not regulate the safety of foods for pets or livestock. The cat food was irradiated with ≥ 50 kGy, i.e. at least 50 times higher than the maximum dose sought by the applicant in the current application. FSANZ's conclusion that the effect is specific to cats is based on the following observations: • some of the cats became ill after eating dog food made by the same company and irradiated at the same doses, whereas no dogs fed that dog food developed any adverse effects • no similar effects have been observed in rodents fed irradiated diets for multiple generations • no similar effects have been observed in human beings consuming irradiated diets for prolonged periods, including astronauts and patients with severe immunodeficiency disorders. The cat is well-recognized to have unique metabolism of many chemicals (Court 2013)[10] and for this reason, is not used as a model for human safety studies. The toxicity of highly irradiated cat food to cats has been discussed by FSANZ in previous hazard assessments of irradiated food, and no new studies postdating those assessments, concerning the neurological disorder in cats were identified. For this reason, it was not addressed in the assessment report.
21	**Radiolytic compounds** Submitters provided a number of comments and studies related to radiolytic compounds, free radicals, and toxic chemicals produced by food irradiation. The submitters disagree with FSANZ's assertion that irradiated food is 'chemical free' as irradiation can cause the accumulation of radiolytic compounds (e.g. 2-ACBs, 2-TCB, 2-TDCB and 2-DCB) at levels not observed in non-irradiated foods. These radiolytic products include a variety of	Food Irradiation Watch/Gene Ethics Private individuals Sustainable Agriculture and Communities Alliance (SACA), Victoria	FSANZ has not asserted that irradiated food is 'chemical free'. FSANZ has correctly stated that phytosanitary irradiation is a 'chemical-free treatment'. The treatment itself does not use chemicals. With the exception of 2-ACBs, radiolytic products are also found in other foods, either occurring naturally or being generated by thermal treatment such as cooking, at similar or higher levels than those found in irradiated foods. Consumption of irradiated foods does not result in significantly increased exposure to those chemicals.

[9] https://www.avma.org/javma-news/2009-08-15/australia-halts-irradiation-imported-cat-food-after-link-neurologicdamage.
[10] Court H (2013) Feline drug metabolism and disposition: pharmacokinetic evidence for species differences and molecular mechanisms. Vet Clin North Am Small Animal Pract 43(5):1039-54.

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	mutagens – substances that can cause gene mutations, polyploidy (an abnormal condition in which cells contain more than two sets of chromosomes), chromosome aberrations (often associated with cancerous cells) and dominant lethal mutations (a change in a cell that prevents it from reproducing) in human cells, and can also be carcinogens. Irradiation also causes stunted growth in lab animals fed irradiated foods. Very few of these chemicals have been studied for toxicity. The FDA has never tested the safety of these by-products.		Radiolytic products, including 2-ACBs, are assessed in the Hazard Assessment of SD1. These compounds are not considered to pose a safety concern at the levels found in irradiated fruit and vegetables. This is consistent with previous FSANZ assessments (see Table 1 in SD1). There is no evidence that consumption of irradiated foods leads to increased risk of cancer. FSANZ has undertaken successive risk assessments of irradiated foods, based on peer-reviewed literature including compositional analyses, dietary studies in animals, studies in human populations, and evidence from history of use in human populations. FSANZ has concluded that irradiated fruit and vegetables are safe to consume. This conclusion is the same as that of other regulatory agencies including the WHO, EFSA, and US FDA. FSANZ consideration of specific studies cited by submitters is provided at Attachment 2.1 (d). The wholesomeness of irradiated foods has, therefore, been the subject of considerable international research, which has been reviewed and evaluated by joint expert committees of the IAEA, the WHO, and the FAO of the United Nations. These expert groups have uniformly concluded that the food irradiation process does not present any enhanced toxicological, microbiological, or nutritional hazard beyond those brought about by conventional food processing techniques.
22	**Effects of irradiation on electrical charge** 1. When proteins in food are exposed to radiation they fold open in an incorrect way; this affects how these proteins are able to be recognised and used by the body. The distribution of electrical charge within the protein is also of concern. 2. Science is becoming more aware of the importance of electromagnetic fields in the healthy functioning of living cells and it is unknown whether irradiation could affect this with consequential negative effects on human health. 3. It is possible that irradiation could cause a change in the DNA composition of the food. This would surely change the natural health and healing properties of the foods. 4. Irradiation will expose foods to energy equal to approximately 1.5 million – 10 million X-rays (calculated at the low end of chest X-ray	Private individuals	1. Chronic and multigenerational studies of feeding irradiated diets to animals, as well as prolonged use of wholly irradiated diets by some people (e.g. astronauts, patients with immunodeficiency disorders) show that protein intake from irradiated foods is not impaired. Further, fruit and vegetables do not generally represent major sources of protein in the diet. The submitter has not provided any references to support their claim that irradiation of food proteins causes mis-folding. 2. Irradiated fruits and vegetables do not emit electromagnetic radiation. 3. There is no evidence that phytosanitary irradiation of fruit and vegetables alters the properties of those foods through a change in their DNA. Harvested fruit and vegetables are no longer growing by cellular replication, and therefore changes in DNA are not relevant. 4. This application addresses phytosanitary irradiation of fruits and vegetables for human consumption. The application does not seek permission to irradiate seeds, including seeds intended for germination.

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	exposure). Studies have explored the impact this dose of radiation has on plants. Marcu, Damian, Cosma and Cristea (2013) found that corn derived from seeds exposed to ≤0.5 kGy irradiation did not survive more than ten days. Wi et al. (2007) similarly explored the effects of irradiation on morphological changes and biological responses in plants such as pumpkin. The growth of plants irradiated with 50 Gy, which is less than the amount being put forth in application A1193, was significantly inhibited. 5. The blast from the radiation knocks the electrons from the atoms and molecules. The radiation waves pass through the food without over-heating but changes the molecular structure and DNA of the food. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5820 857/. The long term effects on human physiology is unknown. See: https://tinyurl.com/y33gjeq7 6. One submitter provides a commentary about combined heat/irradiation treatment for fungi and other products (Farkas (1990); Farkas and Roberts (1976); Padwal-Desai et al. (1973)). The submitter states that according to Kim and Thayer (1996), irradiation causes DNA damage.		5. Phytosanitary irradiation has a long history of safe use in human populations. There is no evidence of adverse effects on human physiology. 6. Irradiation treatment of fungi is out of scope for this application, because fungi are neither fruit or vegetables, and do not belong to Kingdom Plantae but to their own Kingdom, Kingdom Fungi.
23	**Allergenicity** 1. The possible allergenic hazards of irradiated foods are not well enough understood. It is not possible to draw conclusions regarding allergenicity of irradiated fruit and vegetables based on the allergenicity outcome of one tree nut. 2. Irradiation has the potential to modify the tertiary structure of proteins, representing the risk of generating allergenic epitopes. Until adequate and conclusive research has been completed to rule out this potential, irradiation should not be used as a processing option for mainstream foods consumed by an increasingly allergenic population.	Private individuals Allergy and Anaphylaxis Australia Wiser Equity Pty Ltd	FSANZ's conclusions concerning the safety of irradiated fruit and vegetables are the same as those of joint expert committees of the IAEA, the WHO, and the FAO as well as other regulatory agencies including EFSA and the US FDA. 1. The conclusion that there is no evidence that irradiation increases allergenicity was not based on the outcome of the study in a nut, in which allergenicity was decreased. The conclusion reached in the risk assessment, that there is no evidence that irradiation increases allergenicity, was based on thorough searches of the scientific literature, as described in SD1. 2. The submitter has not provided a reference relating to their claim that irradiation changes the tertiary structure of proteins, so the relevance to A1193 cannot be assessed. 3. The submitter has not provided a reference to the 'recent study' relating to

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	3. A recent study showed that smaller irradiation dosages (~1 Gy) can render protein more allergenic than either non-irradiated protein, or protein irradiated at a higher dosage. It has been speculated that this effect may be due to increased exposure of conformational and linear epitopes resulting from the formation of partially unfolded and aggregated species in response to irradiation. 4. Prevalence of allergies to vegetables and fruits are low, but not insignificant, and most likely due to reactions to glycoprotein food components. FSANZ and the applicant have still not adequately addressed this concern in either the application or the various responses. 5. As allergies increase, choosing foods that are safe is difficult and with irradiation, the task of buying 'safe' foods will be made more difficult. 6. This country already has one of the highest rates of allergies in the modern world. In France, less than 1% of the population has gluten intolerance or are coeliac because as a country and Government, they respect their soil, food and produce.		irradiation and the allergenicity of proteins, so the relevance to A1193 cannot be assessed. 4. FSANZ has conducted extensive literature searches without locating any evidence that phytosanitary irradiation makes any fruit or vegetable allergenic. 5. There is no evidence that irradiated fruit and vegetables are likely to cause allergic reactions that their non-irradiated counterparts do not cause, and therefore phytosanitary irradiation will not affect the task of finding foods that do not induce allergic reactions. 6. While the reason for the high rate of allergies in Australia is not known, as of 2016, France had five facilities where phytosanitary irradiation of food is conducted, see https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC1104(01)&from=PL. In western countries, the prevalence of coeliac disease is around 0.6% histologically confirmed and 1% in serological screening of the general population. A less than 1% prevalence in France is therefore comparable to other western countries.
24	**Interactions** There is little research on the interaction of irradiation with GMOs, pesticides and other chemicals used in agriculture and food supply chains. FSANZ must guarantee the safety of such interactions. The assessment of fresh fruit and vegetables has not taken into account the anti-nutrients or free radicals formed from the pesticides used on the produce when irradiated and their effects on the person's health over time. There is no data on the composition of each irradiated vegetable including the maximum amounts of contaminants or pesticide residues that may be present in the food. Research by Lepine[11] (1991) has	Food Irradiation Watch/Gene Ethics GE Free NZ	FSANZ has undertaken successive risk assessments of irradiated foods, based on peer-reviewed literature including compositional analyses, dietary studies in animals, studies in human populations, and evidence from history of use in human populations. FSANZ has concluded that irradiated fruit and vegetables are safe to consume. This conclusion is the same as that of other regulatory agencies including the WHO, EFSA and US FDA. FSANZ notes: • The submitter has not provided a plausible mechanism for the interaction of irradiation with GMOs in a manner different to that with non-modified organisms. • The submitter has not provided any evidence that anti-nutrients or free radicals are likely to be formed from remaining pesticide residues. The

[11] Lepine F (1991) Effects of ionizing radiation on pesticides in a food irradiation perspective: a bibliographic review. Journal Of Agricultural And Food Chemistry 39(12), 2112-2118. https://doi.org/10.1021/jf00012a002.

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	found that irradiation of pesticide residues in fruit and vegetables at the level of 150 Gy and higher produces high levels of hydroxyl radicals. Mu et al. (2017)[12] found that hydroxyl radicals in a biological body attack the cell membrane, causing membrane damage and destroying sugar groups and DNA base sequences, inducing the disintegration of the double-helix structure, even causing cell death and mutations.		likelihood of such a reaction posing safety concerns is negligible. • Phytosanitary irradiation may reduce the use of post-harvest pesticide or fumigant use. • Pesticide residues on produce are strictly regulated by the APVMA and monitored. Hydroxyl radicals are highly reactive and unstable, with very short half-lives, and would not be present in irradiated produce at the time of sale. The issue of radiolytic compounds such as hydroxyl radicals has also been addressed in the response to no. 21.
	Safety – nuclear industry and the environment		
25	Submitters raised a number of issues related to the nuclear industry, noting that food irradiation is a branch of the nuclear industry, and there are inherent safety issues regarding transport, commercial use and workplace health and safety. The depleted radioactive waste must be disposed of in a security-conscious manner. Submitters raised a number of environmental issues related to the treatment itself, radioactivity, and pollution. It was noted that accidents at radioactive irradiation facilities have led to radioactive spills and contamination of surrounding land and water resources. Examples of some of the comments include: - Irradiation contributes to more polluting and poisoning of the already fragile environment. - Radiation cannot be guaranteed to be safe for people and for the wider environment. - Irradiation using radioactive material is an environmental hazard. - A failure of seeds to germinate is as a result of irradiation treatment. - Irradiated water was flushed into sewers in the US costing the taxpayer $47m to clean up. See https://rense.com/general81/foodr.htm	Private individuals Academia	Issues concerning the safety of this branch of the nuclear industry, including potential environmental issues, are outside FSANZ's regulatory mandate and are the responsibility of other agencies' legislation. These may include the relevant state/territory environment departments, environment protection authorities and the radiation health/safety areas of health departments. In Australia and New Zealand, there are strict guidelines, standards, and legislation on the establishment and routine operation of irradiation facilities, and use, storage, transport and disposal of radioactive material. In Australia, food irradiation is undertaken using the radionuclide ^{60}Co and, more recently, X-rays, indicating a trend towards use of non-radioactive radiation sources. The radionuclide ^{60}Co source does not produce radioactive waste material but decays over time to produce non-radioactive nickel. The sources can be returned to the supplier for reactivation or reuse in another application. Irradiation does not make the food, or the person eating it, radioactive. The food does not come in contact with the energy source during food irradiation, so it cannot become contaminated by radioactive material. Regarding failure of irradiated seeds to germinate, the application is not seeking permission to irradiate seeds, including seeds intended for germination.
	Nutrition assessment		

[12] Mu T, Sun H, Zhang M & Wang C (2017) Sweet potato processing technology.

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26	Irradiation could adversely affect the nutritional value of significant core components of the Australian and New Zealand food supply. According to The Food Commission, Britain's leading, independent watchdog on food issues, food irradiation can result in loss of nutrients. FSANZ tacitly acknowledges nutrient depletion and justifies acceptance of irradiation-depleted foods by stating the consumers will also be eating non-irradiated, and thus non-depleted, food that will, in essence, make up for the lost nutrients. Fresh fruit and vegetables are important for growth, maintaining health, avoiding illness and healthy ageing. For these reasons the integrity of fruit and vegetables must be kept high and produce should not be exposed to irradiation. We urge FSANZ to [undertake 90 day ingestion studies, ethically approved], examine the changes which occur in the nutrient content of foods following irradiation and determine whether the bio availability of nutrients would have possible adverse nutritional consequences. Nutrition will be devalued to only fibre, without the vitamins, minerals and life force of non-irradiated fruit. This equals mass health starvation. The report states that 'vitamins range from relatively high to low sensitivity to radiation with vitamin C, thiamin, vitamin E and vitamin A being most sensitive'. These vitamins are crucial for human health and even a small loss of these nutrients is concerning.	Academia Private individuals Food Irradiation Watch/Gene Ethics	A general response to submissions that raised concerns regarding the nutritional impact of irradiation on fruit and vegetables is provided below. In evaluating the effect of irradiation on the nutrient content of all fruit and vegetables, FSANZ has focused most of its risk assessment on vitamins that are potentially more sensitive to deterioration and for which fruit and vegetables are important sources in the diet; these were vitamin C and β-carotene. FSANZ made this decision on the basis of previous expert opinions by the WHO which ranked these nutrients as more sensitive to loss when exposed to radiation. These reports also concluded that irradiation does not affect the macronutrient (i.e. protein, carbohydrate, fat, and energy) and mineral content of food. FSANZ has reviewed previously (in Applications A443, A1038, A1069, A1092, A1115 and a 2014 review of the effect of irradiation on fruits and vegetables) the body of evidence for the effect of irradiation on the vitamin C and β-carotene content of a selected range of fruit and vegetables. Conclusions in these assessments were that losses of these vitamins caused by low dose irradiation exposure (up to 1 kG) are small or negligible, but that some inconsistency existed in the results across the studies. These earlier reviews did not seek to calculate or estimate the average effect (i.e. effect size) or variability; therefore, it is not possible to judge the size of the 'small' or 'negligible' losses. In the assessment of the current application (A1193), FSANZ has taken a quantitative approach (i.e. meta-analysis) to evaluating the body of evidence and estimated that the average loss of vitamin C in green leafy vegetables, brassicas, and roots and tubers that are irradiated (up to 1 kG) is 2 mg per 100 g, or approximately 5%; for β-carotene, the loss is 3 mg per Kg, or approximately 3%. The weight of evidence which has been reviewed and evaluated by FSANZ – across the many applications – suggests that losses of vitamin C and β-carotene in fruit and vegetables that are irradiated are small; however, there is imprecision and inconsistency in the results across the body of evidence. This inconsistency is not an important concern because it is expected that less than 8% of the fruit and vegetables in the food supply will be irradiated minimising any impact on population nutrient intakes from consuming irradiated produce. This figure has been determined using estimates provided by the applicant based on their knowledge of phytosanitary treatments and commodity trade in general, and in consultation with the irradiation industry, having the practical knowledge of phytosanitary irradiation treatments in Australia. No evidence to the contrary was provided by submitters (including the relevant biosecurity agencies) or located

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			by FSANZ.
27	Question the rationale behind reducing food nutritional value to increase profits.	Private individual	Multiple independent assessments were conducted by FSANZ, including the current assessment and others listed in Table 1 of SD1. FSANZ concluded that based on the available evidence that the effect of irradiation on the micronutrient intake of fruit and vegetables is likely to be low.
28	It is widely understood that irradiation may alter the dietary composition of food. Queensland Health acknowledges that 'Vitamins A, B1 (thiamin), C, E and K in foods are relatively sensitive to radiation'[13].	Academia	See responses above.
29	The nutritional integrity of irradiated foods has not been established and nutritional aspects require more extensive research. Studies have not been done showing the effect of irradiation on all vitamins.	Academia Private individuals Food Irradiation Watch/Gene Ethics	FSANZ undertook an assessment of the effect of irradiation on irradiation-sensitive vitamins based on previous expert opinions by the WHO which ranked these nutrients as more sensitive to loss when exposed to irradiation. These reports concluded that irradiation does not affect the macronutrient (i.e. protein, carbohydrate, fat, and energy) and mineral content of food (see Section 4.1 of SD1).
30	The nutritional value/quality of irradiated fresh fruit and vegetables is diminished. People will need to eat more food to obtain the same level of nutrients, meaning that society will become even more overweight/ obese. The nutritional value of produce is already compromised due to commercial agriculture, soil health and pesticide poisons. Additionally, research is showing that climate change is already having effects on the nutrient content in some food crops and irradiation would further deplete nutritional value of food. Any treatment that further jeopardises this, even if slightly, will be detrimental to health. Australian soil is known worldwide for its lack of important minerals and vitamins as it is. Our crops are already nutritionally deficient and we don't need to contribute more to this with irradiation. The resulting nutrient deficiencies can leave us more vulnerable to viruses and disease (e.g. as we saw this year with Coronavirus) as well as tooth decay, and problems with immune systems among other concerns. There will be increased costs to the health system in	Private individuals	The current nutrient content of fruits and vegetables are compiled in the latest Australian and New Zealand food composition databases. These data are then used to estimate population dietary intakes as part of national nutrition surveys. Results from these national nutrition surveys in Australia and New Zealand show that only small proportions of the population currently have inadequate intakes of irradiation sensitive nutrients (as outlined in SD1). The nutrition survey results also indicate the variety of foods that contribute to the intake of any individual nutrient, as presented in the dietary intake assessment in SD1. Whilst some published studies have indicated losses in nutrient content of some irradiation sensitive nutrients in some commodities, other factors in the dietary intake assessment were taken into consideration to conclude that there would be minimal impact on population nutrient intakes and that a detailed dietary intake assessment was not required. These factors included information from food composition datasets which shows that nutrient concentrations in fruit and vegetables post-irradiation are within naturally occurring ranges; changes in nutrient content of fruit and vegetables as a result of irradiation may be less than those for fruit and vegetables as a result of storage, processing and cooking; nutrient losses as a result of processing and storage are already taken into account in the estimation of population intakes through incorporation into food composition tables; and only a small proportion of fruit and vegetables would be irradiated.

[13] Queensland Health (2018), The Facts about Food Irradiation. https://www.health.qld.gov.au/__data/assets/pdf_file/0028/721486/food-irradiation.pdf.

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	treating people with potentially increased health problems due to consumption of food whose nutritional values are depleted by irradiation.		
31	See: Ionizing radiation effects on food vitamins – a review (the sensitivity of vitamins to radiation is unpredictable and food vitamin losses during irradiation are often substantial.) https://tinyurl.com/y5jg9kg3	Food Irradiation Watch/Gene Ethics Private individuals	The publication provided by the submitter (Dionisio et al. 2009) is a narrative review that discusses other food irradiation reviews and some studies that measure the effects of irradiation on several foods including fruit and vegetables. It includes results from studies of irradiation at doses outside the 0.15 to 1 kGy dose range that is being considered in this assessment, that are used to inhibit sprouting or to prevent microbiological spoiling. The review reports similar findings to the current assessment for the 0.15 to 1 kGy dose range. The author notes that in cases where losses are observed, these are dependent on storage time, temperature or maturation stage. The two exceptions noted in the study were in fresh-cut lettuce, which is unlikely to be irradiated in this assessment, and star fruit. The author concluded that 'in general, low dose irradiation (under 1 kGy) treatments do not cause significant alterations in vitamin contents of food'.
32	FSANZ acknowledges that irradiation may deplete the vitamin and nutritional content and value of food; but depletions are repeatedly said to be insignificant, the amount of irradiated food produced and consumed is projected to be small, and/or the irradiated foods will contribute little to the community's overall dietary intake. However, there is nothing to limit the expansion of irradiation if ALL fruits and vegetables are approved. As Australians and New Zealanders increasingly adopt plant-based diets (2.5 million or 12% now almost all the food is vegetarian[14]) these arguments for incaution are indefensible. It is irresponsible to be introducing legislation which reduces the health benefits of these foods.	Food Irradiation Watch/Gene Ethics Private individuals	The scope of the application and therefore the assessment was the phytosanitary irradiation of fresh fruit and vegetables at doses ranging between 150 Gy to 1 kGy. Any proposed changes to the Food Standards Code (the Code), including an expansion to the permitted uses of irradiation, would require a new application/proposal demonstrating safety and including adequate technological justification. There are constraints preventing ALL fruits and vegetables from being irradiated. These include cost, capacity, consumer acceptance and supply chain logistics. Our current understanding of the proportion of fruit and vegetables to be irradiated can be monitored and, if they change markedly, a reassessment can occur. If consumers are following vegetarian or plant-based diets and therefore eating a greater proportion of fruit and vegetables in their diet, this will provide a source of micronutrients. Plant-based diets will also include juices, cereals, legumes, nuts and seeds, which also provide a source of nutrients such as thiamin, vitamin A, vitamin C, vitamin E and folate (see SD1 for more information on dietary sources).
33	Irradiation has been shown to deplete vitamins A, B, C, E and K, proteins, essential fatty acids and other	Food Irradiation Watch/Gene Ethics	The quoted text from the Center for Food Safety (and not the FDA as one submitter noted) states that "up to 80% of vitamin A in eggs, up to 95% of the

[14] http://www.roymorgan.com/findings/7944-vegetarianism-in-2018-april-2018-201904120608.

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	nutrients in food. According to the Center for Food Safety[15] in the United States, irradiated foods can lose from two to 95% of their vitamin content. The FDA noted that up to 80% of vitamin A in eggs, up to 95% of the vitamin A and lutein in green beans, up to 50% of the vitamin A and lutein in broccoli and 48% of β-carotene in orange juice was destroyed. This has been linked to health problems such as nutritional deficiencies, immune system disorders, abnormal lymph cells, and genetic damage. This could impact child development and health of pregnant women in particular, who have a high need for these nutrients. Increased approvals will see increased exposure to these risks. For this assessment, FSANZ has found that spinach and rocket have greater than expected sensitivity to radiation, incurring significant nutrient loss. We urge FSANZ to establish whether changes would have possible adverse nutritional consequences on vulnerable members of the community, especially children to meet the RDI.	Private individuals Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ	vitamin A and lutein in green beans, up to 50% of the vitamin A and lutein in broccoli and 48% of β-carotene in orange juice was destroyed" but does not provide scientific evidence to substantiate this claim. The current position of the US FDA is supportive of food irradiation and states that "irradiation does not compromise nutritional quality, change the taste, texture, or appearance of food", see https://www.fda.gov/food/buy-store-serve-safe-food/food-irradiation-what-you-need-know. A comprehensive review of the scientific literature was conducted by FSANZ on the nutritional impact of irradiation on fruit and vegetables, see Section 4 of SD1. The dietary intake assessment considers the Australian and New Zealand populations, which includes subpopulations with varied eating habits and demographics, including children. Based on a range of factors considered in the dietary intake assessment (as outlined in SD1) FSANZ concluded that there would be minimal impact on nutrient intakes.
34	Scientific studies have shown that irradiation destroys up to 96% of vitamins A, B, C, E and K along with other essential nutrients. The Food Commission, Britain's leading, independent watchdog on food safety, stated in July 2002, that food irradiation can result in loss of nutrients. For example, vitamin E levels can be reduced by 25% after ionising radiation, and vitamin C by 5-10%[16].	Sustainable Agriculture and Communities Alliance (SACA), Victoria	No details of the studies referred to by the Food Commission were provided by the submitter or on the Food Commission website so it is not possible to review that information to determine whether they show the claimed results. For this and previous applications undertaken by FSANZ a comprehensive review of the scientific literature was conducted and used as evidence in this assessment to determine the effects of irradiation on the nutrient composition of food. The weight of evidence indicates that there are no new public health or safety concerns that need to be addressed as part of the current application.
35	FSANZ claims that 'there would be no impact on dietary intakes from consuming irradiated produce', however this is contradicted by FSANZ's own findings regarding the impacts on vitamins including vitamin C: '*Across all vegetables, the overall mean decrease in vitamin C content was 2 mg/100 g (95% CI; -3 to -1), representing approximately a 5% loss. The only*	Food Irradiation Watch/Gene Ethics	Whilst some published studies have indicated losses in nutrient content of some irradiation sensitive nutrients such as vitamin C and β-carotene in some commodities, other factors considered in the dietary intake assessment were taken into account in concluding that there would be minimal impact on population nutrient intakes. These factors included that fruit and vegetables contribute only a proportion of total dietary vitamin C and β-carotene intake and only a small proportion of fruit and vegetables would be irradiated. The impact of

[15] https://www.centerforfoodsafety.org/issues/1039/foodirradiation/about-food-irradiation.
[16] http://www.foodcomm.org.uk/campaigns/irradiation_concerns/.

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	exceptions across the eleven types of vegetables assessed were spinach and rocket where the mean loss in spinach was 10 mg/100 g (95% CI; -15 to -6), representing an 18% loss and in rocket 6 mg/100 g (95% CI; -7 to -5) representing a 34% loss. Losses in β-carotene or carotenoid content of leafy vegetables and roots and tubers after irradiation were very small with an overall mean decrease of 3 mg/kg (95% CI; -8 to +3); representing approximately a 3% loss.'		vitamin losses in specific commodities was investigated by FSANZ (see Section 5.2.2 in SD1) and were shown to contribute a small proportion to total dietary intakes of the nutrient (i.e. 0.4% or less of vitamin C intakes from rocket and spinach). The applicant provided information indicating that for many commonly consumed fresh produce items, including salad leaf, the use of irradiation to meet quarantine requirements and/or industry needs would be of low commercial significance. In addition, the expected use of irradiation on these produce items to balance seasonal supply and demand would be on a rare or emergency trade need basis only. This information is based on the applicant's knowledge of phytosanitary treatments and commodity trade in general.
36	FSANZ makes incorrect assertions about vitamin A (retinol) (specifically mentioned in the TGA regulatory guidelines)[17] which is highly sensitive to irradiation excluding it from the assessment '*because retinol is not present in plant foods'*. This is incorrect as retinol is an active form of vitamin A. Carotenoids are dark-coloured pigments found in plant foods that can turn into active form of vitamin A.	Food Irradiation Watch/Gene Ethics	Vitamin A exists as two forms in food, pre-formed retinol and the precursor to vitamin A – carotenes including β-carotene. The two forms of vitamin A have different sensitivities to irradiation. Vitamin A (retinol) is highly sensitive to irradiation but is not present in fruit and vegetables. Provitamin A (β-carotene), which can be converted to retinol in the body is found in some fruit and vegetables and has medium sensitivity to irradiation (see Figure 1 in Section 4.1.1 of SD1).
37	FSANZ fails to address key nutritional issues due to an acknowledged lack of scientific evidence regarding highly sensitive compounds thiamin and vitamin E by stating *'a firm judgement about the extent of irradiation-induced losses is not made because too few relevant studies were identified.'* The disregard for a 'small' (10-17%) source of nutrients that are highly susceptible to irradiation (vitamin E and thiamin) is very concerning and should not be ignored. The decrease in vitamin E in the population could lead to deficiencies which could cause nerve and muscle damage. A reduction in the dietary intake of thiamin could lead to beri beri or Wernicke-Korsakoff syndrome. On page i of the 'supporting document' also appears the principle that 'the maximum absorbed dose should not compromise the properties of the food'. FSANZ itself states that irradiation decreases vitamin levels. Not to mince words, any decrease in a food's	Food Irradiation Watch/Gene Ethics Private individuals Wiser Equity Pty Ltd Consumers SA Sustainable Agriculture and Communities Alliance (SACA), Victoria	FSANZ undertakes a risk assessment based on the best available scientific evidence. The majority of research on the effects of irradiation on thiamin content was undertaken in foods that are high contributors to thiamin intake, including meat and grains, and using doses greater than 1 kGy. A small proportion of thiamin and vitamin E in the Australian and New Zealand diet comes from fruit and vegetables; ~10% for thiamin and 15-24% for vitamin E. The data for vitamin E shows a contribution of vegetables to intakes of 10-17%. Some of the vitamin E in this category comes from fats and oils used during cooking and potato based snack foods. The lower end of the range for vegetables is Australian data, and the upper end of the range from New Zealand. The New Zealand data includes vegetable based snack foods such as potato crisps which were classified within the vegetable category for the New Zealand nutrition survey, and contribute 5.5% for children and 1.9% for adults. Therefore the contribution from vegetables only (no snacks, no oil) will be lower than the values shown. The major contributors to thiamin intakes for Australia and New Zealand are cereal and cereal based products and dishes (see SD1 for further details)

[17] Australian Government, Department of Health, Therapeutic Goods Authority, Australian regulatory guidelines, Information required in an evaluation of a substance for use in listed medicines, Version 1.0, May 2020, p14.

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	micronutrients — including retinol, vitamin C, vitamin E, thiamin, and ß-carotene — compromises its properties. By FSANZ's own evidence, the proposed doses violate FSANZ's principles. Moreover, the applicant has provided no evidence that ionising irradiation will not result in catastrophic degradation of thiamin and vitamin E.		therefore providing a major dietary source of thiamin. The major contributors to vitamin E intakes include cereal based products and dishes, fats and oils, and meat products and dishes in addition to vegetables (see SD1 for further details) therefore there are other major dietary sources of vitamin E. The body of evidence, albeit limited in size, shows that the effect of irradiation on vitamin E and thiamin content of fruit and vegetables is small. When this is combined with considerations in the dietary intake assessment, including that only a small proportion of produce will be irradiated, FSANZ concludes that irradiation of fruit and vegetables will have minimal impact on population intakes of thiamin and vitamin E. Also see the response to submission no. 26.
38	The application states that only impacts on vitamin C and β-carotene are relevant however, there is no satisfactory evidence that folate integrity is maintained in fresh fruits and vegetables subjected to irradiation. Until there is published peer-reviewed evidence that folate is not adversely affected, humans should not be subjected to experimental science that could plausibly seriously affect in utero development, for example increasing neural tube defects, especially as the preferred source of folate is fruits and vegetables.	Wiser Equity Pty Ltd Private individual	The sensitivity of vitamins to irradiation was determined following research on the effects of irradiation on nutrient content in food (see page 26 of SD1). Several early studies on the effect of irradiation on folate content in a range of foods were undertaken[18, 19, 20, 21, 22] and based on these findings the WHO concluded that folate had low sensitivity to irradiation compared to other water soluble vitamins, although it noted that further research was required[23, 24]. Since that time additional studies have been undertaken. In 1995 one study examined the effect of 2.5 kGy, 5 kGy and 10 kGy irradiation on spinach, green cabbage and Brussels sprouts. The 2.5 kGy dose caused around 10% loss of total folates with a dose response relationship observed in most cases indicating that in samples irradiated with up to 1 kGy losses were likely to be less than 10%[25]. Another study[26] found losses of 6-17% in two varieties of baby-leaf spinach

[18] Hozova B and Sorman L (1986) Combined effect of heat sterilization and ionizing radiation on folacin in canned food. Bulletin Potravinarskeho Vyskumu 25(5):351-356.
[19] Richardson LR, Martin JL, Hart S (1958) The activity of certain water-soluble vitamins after exposure to gamma radiations in dry mixtures and in solutions. The Journal of nutrition 65(3): 409-418.
[20] Thayer DW (1990) Food irradiation: benefits and concerns. Journal of food quality 13(3):147-169.
[21] Vakil UK, Aravindakshan M, Srinivas H, Chauhan PS, Sreenivasan A (1973) Nutritional and wholesomeness studies with irradiated foods: India's program. In Radiation preservation of food.
[22] Day HD, Sauberlich HE, Salmon WD (1956) Radiation effects on water soluble vitamins in raw beef. Federation proceedings 15 (3): 921-923.
[23] Proceedings Series, International Atomic Energy Agency, Vienna pp 673:701.
[24] WHO, World Health Organization (1981) Wholesomeness of irradiated food. Joint FAO/IAEA/WHO Expert Committee on Food Irradiation. WHO Technical Report Series 659. WHO, Geneva.
[25] Müller H and Diehl JF (1996) Effect of ionizing radiation on folates in food. LWT-Food Science and Technology 29(1-2):187-190.
[26] Lester GE, Hallman GJ (2010) γ-Irradiation dose: Effects on baby-leaf spinach ascorbic acid, carotenoids, folate, α-tocopherol, and phylloquinone concentrations. Journal of Agricultural and Food Chemistry 58:4901–4906.

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			when stored in air following 1 kGy irradiation, and losses of 18-23% when stored in nitrogen. A study by Pinela et al. (2019)[27] found that total folate content of 45 fresh watercress samples irradiated with 1 kGy increased by 23% when stored at 4° C for 7 days following irradiation compared to control samples and the total folate concentration decreased by 6% in 45 buckler sorrel samples irradiated with 1 kGy and stored at 4° C for 12 days. Overall, the results from these studies involving a few types of vegetables suggest that folate in fruit and vegetables may be sensitive to irradiation, with losses generally less than 20%. Although losses in folate due to irradiation have been observed in some studies, this will have minimal impact on dietary intakes of folate overall and the degree of inadequacy in the population because only a small proportion of fruit and vegetables will be irradiated and fruit and vegetables contribute only a proportion of folate intake.
39	Claims that macronutrient content are unaffected is also incorrect and misleading. Irradiation causes substantial documented changes to both proteins and lipids.	Wiser Equity Pty Ltd	The submitter did not provide any evidence to support their statement. The available evidence indicates that low and medium doses of irradiation (up to 10 kGy) do not cause changes to macronutrients, a position that is supported by the WHO (see Section 4.1.1 of SD1).
40	A US Department of Agriculture study showed that not only did irradiated pork lose some thiamin content, but when the pork was cooked, there was greater additional thiamin loss than occurred in cooked pork that had never been irradiated.	Sustainable Agriculture and Communities Alliance (SACA), Victoria	The effect of irradiation on foods other than fruit and vegetables are outside the scope of this application.
41	There is a lack of scientific research and data into the impact of the loss of phytonutrients in foods that are irradiated. Can FSANZ be certain irradiation will not destroy the molecular structures of vitamins and other phytonutrients, and thereby destroy their capacity to function as required within our bodies? The application fails to address critically important flavonoids found in vegetables and fruits and have been linked to risk reduction/prevention of a range of cancers and coronary heart disease. No evidence is provided that these are not modified when exposed to irradiation.	Health practitioner Private individual Wiser Equity Pty Ltd	The effect of irradiation on vitamins has been discussed at length above and in Section 4 of SD1. Fruit and vegetables are also rich sources of phytonutrients such as flavonoids. These compounds do not have recommended daily intakes and less is known about the level of intake within Australia and New Zealand or about their direct effects on health. Similarly, less is known about the sensitivity of these compounds to irradiation, but given the diversity of compounds the degree of sensitivity is likely to be varied. FSANZ has not identified reliable evidence that indicates that there are nutritional risks that may be mediated by possible changes to phytonutrients in irradiated fruit and vegetables. In addition, as only a small proportion of produce will be irradiated, FSANZ concludes that it is likely that irradiation of fruit and vegetables will have minimal impact on population intakes of phytonutrients.
42	FSANZ's comparisons of nutrient losses due to irradiation against those due to other food processes	Food Irradiation Watch/Gene Ethics	FSANZ's judgement about the effect of irradiation on public health and safety is based primarily on the extent to which irradiation may alter nutrient intakes in the

[27] Pinela J, Morales P, Verde SC, Antonio AL, Carvalho AM, Oliveira MB, Cámara M, Ferreira IC (2019) Stability of total folates/vitamin B9 in irradiated watercress and buckler sorrel during refrigerated storage. Food chemistry 15(274):686-90.

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	(storage, processing and cooking) are not valid as the produce purchased and assumed as 'fresh' has already been processed in a way that substantially diminishes its nutrient content and is often further processed (e.g. home cooking) thereby decreasing the nutrients further.	Private individuals Consumers SA	population. FSANZ's judgement about the effect of irradiation on the nutrient content of fruit and vegetables is not based on a comparison of nutrient changes relative to those caused by other factors such as processing, storage, cooking or variation across cultivars. These latter factors are already accounted for when assessing nutrient intakes in a population as they are inherently included in the nutrient composition databases that form the basis of estimating dietary intakes. Fruit and vegetables that are not in their fresh state would not be permitted to be irradiated as a result of the present application. Fruit and vegetables that are destined for further processing (juicing, canning, freezing etc.) are generally lower value produce (i.e., not export quality) and are not candidates for irradiation.
43	The FSANZ report Nutritional impact of phytosanitary irradiation of fruits and vegetables (February 2014) was referenced heavily in A1193 and SD1, however it bases its assessments on evidence tainted with pro-irradiation bias, and un-peer-reviewed and unpublished research findings, that previous applicants and associates have commissioned or conducted. The report is primarily a literature review which draws heavily for validation on unpublished research conducted by the Queensland Government.	Food Irradiation Watch/Gene Ethics	When an applicant seeks approval for irradiation of a food, they must provide FSANZ with the evidence that supports the safety and nutritional adequacy of that food. When undertaking a nutrition risk assessment FSANZ considers published and unpublished data provided by the applicant in accordance with international best practice methods for risk assessment. It is a requirement that this data be generated according to internationally accepted protocols (i.e. validated methodology and procedures that are consistent with Good Laboratory Practice (GLP)) and stand up to external scrutiny (i.e. independent audits and documentation trails). FSANZ also complements the data package provided by the applicant with information from the scientific literature, other applications, other government agencies and the public. In the case of the 2014 review, FSANZ assessed over 100 peer-reviewed scientific publications as well as unpublished studies in its risk assessment, although the submitted data did provide useful contemporary information about the effects of irradiation on nutrient levels in a range of fruit and vegetables.
44	The literature search conducted for A1193 SD1 is an ad hoc and partial set of information. Many of the tests reported measure the impacts of radiation exposure well outside the doses that A1193 proposes to permit. We reject the FSANZ reviews constitute peer-review. There are over 150 different varieties of tropical fruits grown in tropical North Queensland, yet few of these have been tested for the impacts of irradiation on their nutritional value or safety.	Food Irradiation Watch/Gene Ethics	When an applicant seeks approval for the irradiation of a food, they must provide FSANZ with evidence that supports the safety and nutritional adequacy of that food. In addition to the evidence provided by the applicant for A1193, FSANZ undertook a comprehensive search of the scientific literature in accordance with international best practice. Details of the search strategy are provided in Appendix 3 of SD1. Application A1193 requests permission for the use phytosanitary doses of irradiation 0.15 – 1 kGy in fruit and vegetables. Doses higher than 1 kGy may overestimate the effects of irradiation on the requested range while doses lower than 0.15 kGy may underestimate losses. When undertaking a risk assessment FSANZ uses the best available scientific evidence. The effects of irradiation on

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			nutrient loss are considered to be dose-dependent therefore studies that measure the effect of doses outside that range were excluded unless no other data were available, and when used were considered in that context[28].
45	People with food allergy rely heavily on unprocessed foods such as fruit and vegetables. Those with multiple food allergies rely on a much smaller range of foods including fresh fruit and vegetables and their nutrition may therefore be more significantly impacted by irradiation.	Allergy and Anaphylaxis Australia	Although almost any food can trigger a food allergy, 80% of food allergies worldwide are caused by eight foods including milk, eggs, wheat, peanut and tree-nuts, fish and crustacean and sesame. Evidence from the 2011-12 Australian National Nutrition and Physical Activity Survey released by the Australian Bureau of Statistics shows that the most common type of foods reported causing allergy or intolerance were Cow's milk/Dairy (4.5% of respondents), followed by Gluten (2.5%), Shellfish (2.0%) and Peanuts (1.4%). 'Other' foods noted by a smaller proportion of respondents did include some fruit and vegetables such as tomatoes, oranges, bananas and capsicum. A higher reliance on fruit and vegetables and a greater proportion of the diet from these food groups may provide greater micronutrient intakes compared to those provided through the consumption of processed foods. There is evidence that shows that higher fruit and vegetable consumption results in higher micronutrient intakes[29]. Where someone with multiple allergies has a very restricted diet, it is likely they would be under close and regular medical supervision including the care of a dietitian who would be able to undertake a specific and detailed analysis of the person's diet and provide tailored advice on obtaining sufficient intake of nutrients from the foods they can consume or suggest if additional nutritive support was required from other means such as dietary supplements. Only a small proportion of fruits and vegetables will be irradiated, and the treatment will be seasonal so not all fruit and vegetables consumed across the year and over a long period of time would be an irradiated version. Therefore, as for people in the general population, the impact on total dietary intakes for people with allergies is likely to be minimal.
46	There is a lack of adequate testing for biochemical	Private individuals	Numerous studies were undertaken in the development of food irradiation for

[28] Diehl et al. (1991) Regulation of food irradiation in the European Community: is nutrition an issue?. Food control 2(4), 212-219.

[29] Bernstein et al. (2002) A home-based nutrition intervention to increase consumption of fruits, vegetables, and calcium-rich foods in community dwelling elders. *Journal of the American Dietetic Association* 102(10) 1421-1427; Billson et al. (1999) Variation in fruit and vegetable consumption among adults in Britain. An analysis from the dietary and nutritional survey of British adults. *European Journal of Clinical Nutrition* 53 946-952; Duthie et al. (2018) Effect of increasing fruit and vegetable intake by dietary intervention on nutritional biomarkers and attitudes to dietary change: a randomised control trial. *European Journal of Nutrition* 57(5) 1855-1872; Macdonald et al. (2009) Changes in vitamin biomarkers during a 2-year intervention trial involving increased fruit and vegetable consumption by free-living volunteers. *British Journal of Nutrition* 102(10) 1477-1486.

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	changes to food quality and nutrient value, which may affect the consumer. Irradiation causes physical-chemical and biochemical changes that may affect nutritional value. There is no science on how well the nutrients in the irradiated food are absorbed by the body.		sanitary and phytosanitary purposes, indicating that the calorific value of food is not reduced, changes in sugars, fats, proteins and enzymes are minimal and losses of vitamins are in general small[30, 31]. Irradiation at doses greater than 0.6 kGy can result in softening of fresh fruit and vegetables however this can be overcome by processing at low temperature or under an inert atmosphere[32]. No human studies on the bioavailability of nutrients in food following irradiation are available and conclusions were based on the nutrient content of food.
	Dietary intake assessment		
47	FSANZ contradicts itself by acknowledging the impacts of irradiation on the diet and then downplaying them. Its lack of scientific rigour is demonstrated by its vague estimation that impacts on the micronutrient content of fruit and vegetables are 'likely to be low'. There is a cumulative effect of one flawed assumption after another – 'likely', 'estimates', 'conservative estimate', ... and then the unjustified conclusion that, as a result of these rubbery estimates, the risk ... is of no practical concern.	Food Irradiation Watch/Gene Ethics Private individual	FSANZ has undertaken a comprehensive assessment of the nutritional impacts of irradiating fruit and vegetables, which included an assessment of post-irradiation changes to the nutrient content of fruit and vegetables and potential impacts on total dietary intakes in the population. This assessment is outlined in detail in the SD1. All reported intakes of nutrients or dietary exposures to other food chemicals are described as 'estimates'. This is because of the inherent limitations and uncertainties associated with the data used for scientific risk assessments. Terms such as 'likely' can be used where there are some uncertainties in the assessment and it is not possible to make a more definitive conclusion. For national nutrition surveys, the limitations of collection methods and data have been well documented. Despite this, the risk assessment is based on the best available data that can be used to produce population nutrient intake estimates and provide reliable figures from which to base risk management decisions. Conservative assumptions are a common aspect of the tiered approach to dietary exposure assessments and are part of international best practice methodologies. The aim of dietary exposure assessments is to make the most realistic estimation of dietary intake/exposure as possible. However, where uncertainties in the data exist, conservative assumptions are generally used to ensure that the estimated dietary exposure is not an underestimate of exposure and therefore is more protective of public health and safety.
48	FSANZ focuses its dietary intake assessment on vitamin C and β-carotene, asserting that a *'detailed dietary intake assessment was not required for these'* claiming that its 2014 review covers most relevant impacts.	Food Irradiation Watch/Gene Ethics	Before approvals are granted, FSANZ undertakes a comprehensive review of the nutritional impacts on foods requested to be permitted to be irradiated. This assessment also considered the information in and conclusions from previous irradiation applications and the 2014 review. In order to make an overall conclusion the nutrient content data must be considered in the context of the

[30] Urbain WM (1986) Radiation chemistry of food components and of foods. Food irradiation Academic Press Inc London, UK 37-82.
[31] Romani RJ (1966) Radiobiological Parameters in the Irradiation of Fruits and Vegetables. Advances in food research 15:57-103.
[32] WHO, World Health Organization (1994) Safety and nutritional adequacy of irradiated food. WHO, Geneva.

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			dietary intake assessment. Refer to response to no. 30, noting also that fruit and vegetables contribute only a proportion of total dietary intake for vitamin C and β-carotene and only a small proportion of fruit and vegetables would be irradiated.
49	FSANZ asserts that because impacts will be low, there is no need for detailed dietary modelling. However, only detailed and cumulative dietary modelling could provide the necessary evidence and assurance that the impacts will be low. The application is being assessed in isolation from its total dietary context and does not take into consideration the long term cumulative effects.	Food Irradiation Watch/Gene Ethics Private individuals GE Free Northland	FSANZ acknowledges the importance of assessing the cumulative effect of the proposed irradiation permission on the total diet of Australian and New Zealand consumers. FSANZ conducted a dietary intake assessment and concluded that there would be no impact on dietary intakes from consuming irradiated produce. Only a small proportion of fruit and vegetables in Australia and New Zealand will be irradiated. Therefore, the dietary intake of nutrients is likely to come from a mix of non-irradiated and a small amount of irradiated produce over the course of a lifetime. This minimises any long term cumulative impact on population nutrient intakes from consuming irradiated produce. FSANZ estimated the nutrient contribution from the commodities with available nutrient impact data compared to the contribution from all fruits and vegetables for vitamin C and β-carotene, and assessed if nutrient impact data were available for the most commonly consumed commodities. This enabled FSANZ to evaluate if the extrapolation of the conclusions from certain commodities to all fruit and vegetables was based on a representative body of evidence. A large proportion (55-85%) of the contribution that fruit and vegetables make to vitamin C and β-carotene intakes in Australia and New Zealand comes from commodities that have nutrient impact data, and there are data for the most commonly consumed commodities (particularly where they contribute highly to nutrient intakes) (see more details in Section 5.2.6 of SD1). Therefore, the final conclusion that irradiation of fruit and vegetables will have minimal impact on population nutrient intakes, can be extrapolated to be relevant for all fruit and vegetables including those where no nutrient impact data are available.
50	Previous applications have been justified partly on the basis of the relatively low intake per capita of approved foods. The applicant has not taken the opportunity to collect comprehensive and credible data following on from FSANZ's previous approvals.	Food Irradiation Watch/Gene Ethics	FSANZ's comprehensive search and evaluation of the scientific literature did not identify any studies which revealed potential harmful effects to humans from consumption of irradiated foods. FSANZ reviewed both unpublished data submitted by the applicant and published studies. The weight of evidence of the existing database, plus data on the safety of irradiated foods that has become available since the initial FSANZ assessment conducted in 2002, indicated that there were no new public health or safety considerations that need to be addressed as part of the current application.
51	The assurance of preserving adequate nutrition from food is based on an estimate only, of proportion of	Private individuals	1. Irradiation of fruit and vegetables will be limited for a phytosanitary purpose only and within a prescribed dose range. This effectively limits irradiation to that

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	overall food to be consumed. 1. How will this proportion be monitored and regulated? Will there be limits on the amount/proportion of irradiated food to be allowed into the food supply? 2. What about individual members of the population who consume greater amounts of irradiated food due to their particular source of supply?		small proportion of domestically produced and imported fruit and vegetables that requires irradiation as a phytosanitary treatment to allow its movement into another quarantine region. Enforcement against the requirements of Standard 1.5.3 is the responsibility of the relevant Australian and New Zealand enforcement agencies. For the reasons stated elsewhere, the above described use of irradiation will result in a small proportion of fruit and vegetables in the food supply being irradiated. All food standards specified in the Code can be reviewed and amended if necessary should credible new information arise after permission was originally granted. 2. Only a small proportion of fruit and vegetables will be irradiated, and the treatment will be seasonal so not all fruit and vegetables consumed across the year and over a long period of time would be an irradiated version. Therefore, the dietary intake of nutrients is likely to come from a mix of non-irradiated and a small amount of irradiated produce over the course of a lifetime. This minimises any long term cumulative impact on nutrient intakes from consuming irradiated produce.
52	It is critical that everyone has access to healthy and fresh foods. The standard of nutrition in some nursing homes is below par. If the application is approved, nursing home residents will not have access to fresh foods as they have been 'pre-cooked'. Other at-risk groups include those with compromised immune systems and those recovering from cancer treatment. Access to healthy and fresh foods should not be compromised at all.	Private individual	The nutrition provided in nursing homes is not in scope. Only a small proportion of fruit and vegetables will be irradiated. FSANZ concludes that irradiation of fruit and vegetables will have minimal impact on nutrient intakes. See also response to no. 13 that notes food irradiation has an established history of safe use in immunosuppressed people.
53	No long term trials on the human consumption of an irradiated diet have been conducted. It is widely understood that irradiation may alter the dietary composition of food. Queensland Health acknowledge that 'Vitamins A, B1 (thiamine), C, E and K in foods are relatively sensitive to radiation' (QH, 2018).	Private individual Academia	See the response to submission no. 11 regarding the safety associated with long term consumption of irradiated produce. Assessment of possible future applications to irradiate food will include consideration of the aggregate effect of all existing irradiation permissions on the total diet of Australian and New Zealand consumers. The impact of vitamin losses in specific commodities for irradiation sensitive nutrients was investigated by FSANZ (see Sections 4 and 5.2.2 in SD1) and were shown to contribute a small proportion to total dietary intakes of the nutrient. FSANZ determined that there would be minimal impact on population nutrient intakes.

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	Technological justification		
54	Irradiation is a quality alternative to Methyl Bromide (MeBr) fumigation and use of certain insecticides that are becoming more restricted or being phased out.	Biosecurity Tasmania	Noted.
55	Neither the applicant nor FSANZ have established/ proven a technological 'need' for using irradiation as a phytosanitary measure for all fresh fruits and vegetables, to meet quarantine requirements. Numerous alternative management practices, processes, and technologies already exist for the same purpose.	Food Irradiation Watch/Gene Ethics	This issue has been addressed in Section 2 of SD1. FSANZ's assessment of earlier irradiation applications and now Application A1193 concludes that phytosanitary irradiation is technologically justified and effective in achieving its stated purpose. FSANZ has been advised by the relevant quarantine authorities that irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests and would provide an effective alternative to currently used disinfestation methods. It is currently considered by the quarantine agencies to be the preferred option to access markets in other countries. Industry has advised FSANZ that while other options exist, these may be unsuitable for use in certain circumstances due to potential phytotoxicity and quality issues. In such circumstances irradiation is a feasible alternative. No credible evidence to the contrary was provided by submitters or located by FSANZ.
56	In 2019, NZ MPI stated that there have been only 5 Queensland fruit flies found and eliminated in the last decade. Another 2 were discovered and eliminated in 2020. This means that existing phytosanitary methods are appropriate for the control and detection of the Queensland fruit fly and the risks are negligible.	GE Free NZ	FSANZ cannot comment on the exact number of detections of fruit fly in New Zealand, but does note that irradiation is already an option for a number of fresh commodities imported into New Zealand from Australia. As of September 2020, import health standards were in place for capsicum, grapes, papaya, lychee (litchi), mango and tomato (see Table 2 of SD1). As such, it could be argued that irradiation as a phytosanitary measure has contributed to New Zealand's overall success in preventing fruit fly incursions. It should also be noted that irradiation is being used to control other insect pests and not just fruit fly. As mentioned in the response to no. 55 above, while other options exist, these may not always be suitable. Therefore, any additional methods for the control of fruit fly are seen as valuable. Supportive submissions were received from New Zealand government agencies (New Zealand Food Safety, part of MPI) and New Zealand food industry groups (New Zealand Food and Grocery Council, Southern Cross Produce New Zealand and Seeka New Zealand).
57	It appears that FSANZ has evaluated the minimum dose of 150 Gy, purporting no harm, but is allowing a	GE Free NZ	Currently, section 1.5.3—3 of the Code permits the irradiation of fruit and vegetables as a phytosanitary measure within the range of 150 Gy to 1 kGy. If

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	range of up 1 kGy. This is a 6.5 fold increase with no supporting dietary evidence of nutritional safety. Two references are provided justifying the submitter's concern that fruit and vegetables are damaged by treatment between 0.25 – 1 kGy. The submitter states that though the assessment considered the extended shelf life of irradiated fruit and vegetables, it did not consider quality, nutritional and anti-nutrient levels in treated fruit.		this application is approved, this dose range will not change. It is an appropriate dose range to enable quarantine agencies to consider irradiation as a treatment, not only for the control of fruit flies, but other insect pests. Section 2.5.1.4 of SD1 provides further details regarding the rationale for setting the maximum dose of 1 kGy. The safety and efficacy of the prescribed dose range has already been comprehensively assessed in earlier irradiation applications, as well as the risk assessment conducted for this application, as detailed in SD1. See also response to no. 26, which provides details on the nutritional impact of irradiation on fruit and vegetables. Use of irradiation will be permitted for a phytosanitary purpose only, not for shelf life extension. The permitted doses are considered insufficient to markedly increase shelf life of fresh produce.
58	If the concern is about food waste, then turn fruit and vegetable waste into compost, which is extremely useful in improving soil fertility etc.	Private individual	The application is seeking permission to use irradiation for a phytosanitary purpose only, not for shelf life extension as a means of reducing food waste.
59	Scientific tests have shown irradiation is ineffective in killing insects and extending the shelf life of fruit. The dosages of ionising radiation needed to kill insects such as fruit fly are too high for most fruits to tolerate and, as such, damage the produce and cause negative organoleptic effects. However, with low dosages, insects are still alive after irradiation. There was mention of New Zealand trials relating to the irradiation of lamb, which caused offensive odour and therefore quality problems.	Sustainable Agriculture and Communities Alliance (SACA), Victoria Friends of the Earth NZ	The submitter has not provided a reference to the 'scientific tests', so FSANZ cannot comment on these particular findings. FSANZ's risk assessment demonstrates the technological justification and efficacy of treating various fruit and vegetables with irradiation as a phytosanitary measure, whereby a minimum dose of 150 Gy can prevent the emergence of adult fruit flies in fruit and vegetables, and a minimum dose of 400 Gy is recognised as a generic treatment for all insects in all host fruit and vegetables (except adult Lepidoptera that pupate internally). In most cases irradiation either kills or inhibits further development of different life-cycle stages of insect pests. Therefore, even if insect pests remain alive post low dose levels of irradiation, they are rendered ineffective. See Sections 2.4 and 2.5, specifically 2.5.1.3 in SD1. The results of trials involving the irradiation of lamb are not relevant because they are referring to animal products rather than fruit or vegetables.
60	There are numerous chemical-free and irradiation-free options for the production of food, which pose little or no health risk to consumers but which FSANZ have ignored. Submitters provided many examples of alternatives to irradiation including: correct maturity bands; host testing to show non-host status; pest exclusion zones; early harvesting; organic production and handling methodologies; ultra-high-pressure	Food Irradiation Watch/Gene Ethics Private individuals Ceres Natural Foods GE Free Northland	For all applications to amend the Code, the scope of FSANZ's assessment is specific to that requested by the applicant. In conducting its comprehensive assessment of the safety and technological justification for the use of irradiation as a phytosanitary measure, FSANZ does not compare the effectiveness of irradiation against other treatments. The relative effectiveness of irradiation versus other phytosanitary methods is a decision for regulatory agencies such as NZ MPI, when they assess the suitability of irradiation as a phytosanitary measure, as part of establishing import health standards for a requested fruit or

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	processing; brushing; waxing; dipping; cleaning or washing; heat/steam vapour treatment; cold treatment; modified atmospheres and vacuum packs; stabilised chlorine dioxide; dilute hydrogen peroxide; ozone; and UV light. In terms of early harvesting, many fruits such as bananas and papaya can be picked at a green stage when they are not hosts for fruit flies. In addition, submitters suggested Integrated Pest Management (IPM) systems and Whole of Systems approaches. The latter requires an orchard management system that involves fruit fly baits, traps, removal of all fallen and over-ripe fruit, as well as having a harvest maturity index from fruits. In sum, there is no technological imperative to irradiate foods, nor a situation in which irradiation is the only choice.	Organic Industries of Australia	vegetable. Irradiation will not be a mandatory treatment under the Code. Rather, it will be only one of a number of phytosanitary treatment options already available from which the horticultural industry may choose, depending on their individual circumstances. Some of the other treatments listed may well be used by the industry in preference to irradiation in certain circumstances. However, industry has advised FSANZ that, in other situations, existing options may be unsuitable due to potential phytotoxicity and quality issues. In such circumstances irradiation is a viable alternative that has been assessed and concluded to be safe and suitable for its proposed purpose.
61	'Good' agricultural practice must take full account of comparative nutritional value and toxicity resulting from the use of other agricultural practices. The applicant has demonstrated no urgent and compelling need to replace conventional methods with ionising irradiation and its consequent nutritional degradation and potential toxicity of foodstuffs. From this and FSANZ's recognition that 'Irradiation as a phytosanitary measure is not a substitute for good hygienic, manufacturing or agricultural practices' follows inexorably the conclusion that X- and gamma irradiation must not be used as a substitute for available hygienic, manufacturing, or agricultural techniques, which are clearly superior to it in every conceivable way.	Private individual	See response to no. 60 above which gives the technological justification for phytosanitary irradiation; response to no. 26 regarding the nutritional impact of irradiation on fruit and vegetables; and response to no. 6 that addresses submitters' concerns regarding toxicity. Irradiation is being proposed as an optional post-harvest phytosanitary treatment. The statement 'Irradiation as a phytosanitary measure is not a substitute for good hygienic, manufacturing or agricultural practices' is intended to convey the point that it is not a substitute for GMP and good agricultural practices (GAP) generally. The statement has been drawn from Codex General Standard for Irradiated Foods (CXS 106-1983, Rev.1–2003), Section 4 – Technological requirements, as follows: *The irradiation of food is justified only when it fulfils a technological requirement and/or is beneficial for the protection of consumer health. It should not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices.* As an example, food irradiation cannot and will not be able to be used for the purpose of cleaning up already spoiled food. The permitted purpose will be phytosanitary treatment only.
62	1. The Forum has long been derelict in its duty to canvass all potential pre- and post-harvest	Food Irradiation Watch/Gene Ethics	1. This is not a matter for FSANZ.

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	management, chemical and technical options to follow the final phase-out of toxic fruit fly insecticides. 2. Irradiation is being promoted as an efficient and affordable 'alternative', and by industry as the go-to substitute, which will give producers access to pest-sensitive markets in preference to other non-chemical alternatives. 3. This is instead of investing in research or setting up pest controls and production practices which would eliminate or lessen the need for post-harvest phytosanitary measures. Organic management systems exist and can be reliably and successfully used for phytosanitary purposes. FSANZ must ensure a whole systems approach is used that would guarantee or at least make accessible – other approaches to quarantine solutions.	GE Free Northland	2. FSANZ does not compare the effectiveness of irradiation against other potential pre- and post-harvest options. The consideration of different phytosanitary treatments remains with the industry and relevant state and territory governments. FSANZ's role in relation to this application is to assess the public health and safety and technological merits of the proposed treatment in accordance with the FSANZ Act. 3. Industry has advised FSANZ that although other options exist to control fruit fly infestation, these may be unsuitable for use in certain circumstances due to potential phytotoxicity and quality issues. In such circumstances irradiation is a feasible alternative. There are costs and time delays associated with getting such approvals and this may make them not as cost effective when compared to irradiation.
63	Irradiated produce will not be chemical-free. Irradiation will not eliminate the use of chemicals and pesticides in crop production as it would be used in conjunction with these and other food production processes including genetic manipulation, cold storage or other processes used on produce, in the planting through harvesting phases of crop production. At best, irradiation may substitute for some post-harvest chemical treatments. Therefore, the assertion that irradiating food provides choice to consumers wanting to avoid exposure to food production chemicals is erroneous.	Food Irradiation Watch/Gene Ethics Private individuals Wiser Equity Pty Ltd	FSANZ does not claim that irradiated produce will be chemical-free, only that the process is chemical-free. Nor does FSANZ claim that irradiation would eliminate the use of chemicals. Further, FSANZ has made no assertion that irradiating food provides choice to consumers wanting to avoid exposure to food production chemicals. Phytosanitary irradiation may reduce the use of post-harvest pesticide or fumigant use. In particular, FSANZ's SD1 states that ionising radiation is a viable and effective alternative to chemical treatments, particularly in cases where such treatments have been restricted or are being phased-out. Examples include the insecticide dimethoate and the fumigant MeBr.
64	New Zealand biosecurity accepts non-irradiated Australian tomatoes provided they are grown in pest-free zones, which are already feasible in most states.	Food Irradiation Watch/Gene Ethics	Phytosanitary irradiation is an effective phytosanitary option for the export of Australian tomatoes into New Zealand that have not been grown in designated pest free areas.
65	Claims that fruits and vegetables are not significantly changed due to irradiation processing are misleading. By extending shelf life supermarkets can earn more, even if nutrition is compromised. Extended shelf life is in contradiction to consumers' desire to have a selection of fresh fruit and vegetables that are 'fresh' and contain essential vitamins and other nutrients.	Food Irradiation Watch/Gene Ethics Private individuals Ceres Fresh Foods	Use of irradiation will be permitted for a phytosanitary purpose only, not for microbial decontamination or shelf life extension. The permitted doses are insufficient for microbial decontamination and they will not markedly increase shelf life. The treatment of fruits and vegetables by irradiation, like other food processing processes, is strictly regulated. Correct dosages are managed by accurate

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	Irradiation may cause food poisoning by killing microorganisms/ bacteria that indicate that food is going bad e.g. bacteria that produce the warning smells indicating that food is going 'off'. Irradiation does not inactivate dangerous toxins which have already been produced by bacteria. Thus, irradiation is a means of deceiving consumers.	Wiser Equity Pty Ltd Organic Industries of Australia	dosimetry and maintenance of records under the requirements of Standard 1.5.3.
66	The International Atomic Energy Agency (IAEA) International Database on Commodity Tolerance (IDCT) is a compilation of research on the impacts of irradiation on fresh horticultural produce[33]. Data is scant for many commodities and much of the research pre-dates the identification of residual radiolytic products. As such, there is no mechanism to ensure that industry will determine or use radiation dosages for particular purposes, products, and/or pests.	Food Irradiation Watch/Gene Ethics	Dosage limits are recommended by the International Consultative Group on Food Irradiation (ICGFI) on the basis of technological data available in the literature. The lowest absorbed dose is the lowest dose that still achieves the desired effect. The highest acceptable absorbed dose is the one beyond which sensory and functional properties of food may be impaired. These values are determined through experience and experimental data, and help define GIP, which is an integral part of GMP. The processing of food by irradiation is one of the heaviest regulated and audited treatments available to industry. Correct dosages are managed by accurate dosimetry and maintenance of records under the requirements of Standard 1.5.3. The application is seeking permission to use irradiation at dosages ranging from 150 Gy to 1 kGy. There is no incentive for industry to use doses that fall outside the permitted range, noting that lower doses will likely be ineffective and higher doses may impair organoleptic properties.
67	This application will potentially open the way for mandatory irradiation. While the current Standard prescribes up to 1 kGy for fruit, FSANZ aims to align with Codex standards which already permit a maximum generic dose of *'up to 10 kGy, except when necessary to achieve a legitimate technological purpose.'* If A1193 is approved, Australia may subsequently push to increase the approved maximum dose of 1 kGy – the dose upon which all assessments to date are premised.	Private individual Food Irradiation Watch/Gene Ethics	The scope of the application and therefore the assessment was the optional phytosanitary irradiation of fresh fruit and vegetables at doses ranging between 150 Gy to 1 kGy. Anything outside of that dose range is not being considered for approval. Any proposed changes to the Code, including to make irradiation mandatory or to increase the approved maximum dose, would require a new application/ proposal demonstrating safety and including adequate technological justification. That application would then have to be assessed in accordance with the FSANZ Act.
	Labelling		
68	Mandatory labelling provides complete power to the consumer to choose or avoid irradiated produce.	Steritech, Queensland	Noted.

[33] https://nucleus-qa.iaea.org/sites/naipc/IDCT/Pages/default.aspx.

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69	The requirement for labelling irradiated fruit should be removed since the public health and safety of such produce is now clearly established. Labelling is an unnecessary cost for both industry and consumers to bear.	New Zealand Food and Grocery Council	FSANZ notes the intent of mandatory labelling requirements for irradiated food is to enable consumers to make an informed choice. In 2011 an independent review of labelling recommended that the requirement for mandatory labelling of irradiated food be reviewed. In their response to the recommendation, Food Regulation Ministers asked FSANZ to review the need for the mandatory labelling of irradiated food, and assess whether there is a more effective approach to communicate the safety and benefits of irradiation to consumers. In April 2017, Food Regulation Ministers considered FSANZ's review report and agreed that no further action was required. Noting the findings of the 2017 review and, as the application is not seeking a change to the labelling requirements, removal of mandatory labelling requirements is therefore out of scope.
70	FSANZ is asked to confirm that food currently irradiated is communicated to consumers at point of sale, and if fruit and vegetables are permitted to be irradiated then this is also likewise communicated.	Allergy and Anaphylaxis Australia	If an irradiated food or a food containing an irradiated ingredient or component is exempt from bearing a label (e.g. unpackaged fruit or vegetables or food sold in a restaurant) then section 1.2.1—9 of the Code requires that the statement that the food (or ingredient and/or component) has been treated with ionising radiation accompany the food or be displayed in connection with the display of the food.
	Already consumers are eating irradiated foods unwittingly and in greater quantities than they realise, not only those being purchased in supermarkets, but also those from food outlets including takeaway and restaurants. In the latter two, labelling is not visible.	Food Irradiation Watch/Gene Ethics Private individuals	
	These three submitters mentioned that they did not support the information for irradiated food being provided on a sign next to the food. Each piece of fruit or vegetable should be separately labelled with irradiation information, and not just be placed 'adjacent to' or 'nearby'.	Consumers SA Friends of the Earth NZ Food Irradiation Watch/Gene Ethics	
71	A statement on pack is supported, and it is important that mandatory labelling requirements are not diluted, with a wider use of irradiation. Industry efforts in the US to label irradiated foods as 'cold-pasteurisation' might confuse and mislead consumers.	Food Intolerance Network	The Code does not prescribe the wording of the mandatory statement. However, Standard 1.5.2 requires a statement with words to the effect that the food has been treated with ionising radiation. This is consistent with the Codex Standard CXS 1-1985.
72	Several submitters mentioned that there must be labelling requirements for the irradiation of food, with: • produce that is irradiated (including imported produce) being clearly marked • this information being full and honest • the requirements being rigorous and onerous.	Food and Beverage Importers Association Private individuals	Existing requirements for labelling information relating to irradiated foods will apply to all fruit and vegetables (including imported produce) permitted to be treated with ionising irradiation. See Section 4.1 of this report.

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73	With the current labelling requirements, consumers may purchase in haste and fail to notice the statements indicating food has been irradiated.	Private individuals	FSANZ has no evidence to indicate consumers do not notice the labelling information for irradiated food.
74	Two submitters expressed concerns with the use of the Radura symbol to indicate that a food has been irradiated. • The logo is not understood by consumers and therefore is inadequate. • At present the Code does not mandate the display of this symbol on the labels of irradiated food. The symbol needs to be mandated and visual on all packaging and on all stands displaying irradiated food, as it is an immediate traffic light signal from which people can be alerted and then make their choice.	Private individuals	The Radura symbol is the international symbol indicating a food product has been irradiated. The Code does not mandate the display of this symbol on the labels of irradiated food, however there is no prohibition on its voluntary use. See Section 4.1 of this report.
75	The following legibility issues were raised: • There is no requirement for minimum size of the labelling. Information is too small to read and noticed only if the consumer is looking for it. • There is no readable, separate label on each piece of fruit. Rather, the irradiation wording and symbol is included on a small brand ID sticker. • The use of different colours rather than black and white impacts on legibility. There should be a moratorium on the sale of any irradiated foods in NZ until the regulations are changed to remedy this [above] ongoing problem. The submission cited an example of a label on individual mangoes designed to not alert the consumer that they have been irradiated.	Friends of the Earth NZ	The statement required for irradiated foods is subject to the generic legibility requirements that also apply to other labelling provisions in the Code (for example, advisory statements, labelling that a food is 'genetically modified'). These requirements are provided in subsection 1.2.1—24(1) of *Standard 1.2.1 – Requirements to have labels or otherwise provide information*, which states that: words must be in English and any word, statement, expression or design must, wherever occurring: (a) be legible; and (b) be prominent so as to contrast distinctly with the background of the label. FSANZ has no evidence that consumers find the legibility of information relating to irradiated food to be problematic and considers existing generic legibility requirements are appropriate. Consumers can contact the relevant food enforcement agency if they consider there are compliance issues.
76	Current regulations do not specify wording for the required labelling statement [on irradiated food], leaving the messaging up to the company. Specifically, the regulations do not prescribe mandatory labelling statements that include 'irradiation', 'radiation', 'irradiated', 'treated with radiation' or 'treated with irradiation'.	Food Irradiation Watch/Gene Ethics Private individuals Consumers SA	The Code does not prescribe the wording of the mandatory statement. However, Standard 1.5.3 requires a statement with words to the effect that the food has been treated with ionising radiation. This is consistent with the Codex Standard CXS 1-1985.

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	Labelling regulations for irradiated food fail by allowing: • wording such as 'treated with ionizing electrons' which may be technically incorrect • few people know that 'ionised electrons' is the same as irradiated • positive statements that may mislead shoppers. One submitter mentioned that in Europe, all foods or ingredients of foods that have been irradiated must be labelled as 'irradiated' or 'treated with ionising radiation'.		
77	For Standard 1.5.3—9, the heading appears to limit labelling requirements to retail and catering. If a retailer buys cases of produce at the markets, and there is no declaration of 'irradiated' on the case, or in accompanying documentation, then the retailer would not declare 'irradiated' on the display.	Private individuals	The Code requires food for retail sale to provide the information that is required by Standard 1.5.3 for irradiated food. Further, the Code requires that a purchaser of a food (for example, a retailer) must be provided with any information necessary to enable them to comply with any compositional, labelling or declaration requirement of the Code (subsection 1.2.1—21(1)).
78	Two submitters mentioned that packaged products made in Australia can consist of a certain percentage of imported ingredients. One of these submitters mentioned that Vietnam (mango, litchi) and India (mango) have begun exporting irradiated fruit to Australia. These submitters queried whether these ingredients or foods will indicate their irradiated status on the label on the package. It is unclear whether or how FSANZ or state authorities will monitor the labelling of irradiated food including food purchased and then used in commercial kitchens, restaurants, juice bars, food supplements, teas, coffee, herbs, spices etc. There is no demonstrated framework for monitoring and enforcement around irradiated fruit and vegetables. What data is available to show that monitoring of labels on irradiated food is occurring?	Consumers SA Food irradiation Watch/Gene Ethics Private individuals	As noted above, foods imported into Australia or New Zealand must comply with the Code, including the labelling requirements for irradiated foods. Monitoring and enforcement of compliance with Code requirements is the responsibility of the relevant enforcement agencies in each Australian state and territory and New Zealand.
79	The required labelling should apply to all irradiated products, whether they are regulated as food, therapeutic goods or agricultural and veterinary products. One submitter noted that irradiated herbs are not labelled when they are used for therapeutic or	Food Irradiation Watch/Gene Ethics Private individual	The Code only applies to food produced for human consumption (FSANZ Act 1991). Therapeutic goods (Australia), medicines (New Zealand) and agricultural and veterinary products fall under different legislation and are outside FSANZ's remit.

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	medicinal purposes, because these are not classified as food products.		
80	Positive statements for marketing purposes should always be accompanied with warnings about the potential impacts of irradiation. FSANZ's role is to regulate, not promote, irradiation but it fails to fulfil its responsibilities to the community.	Food Irradiation Watch/Gene Ethics	The intent of mandatory labelling requirements for irradiated food is to enable consumers to make an informed choice about the food they buy. Irradiated foods are not labelled for safety reasons, as only those foods assessed as safe are approved for sale. Consumer protection legislation prohibits label information that is false, misleading or deceptive. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the Competition and Consumer Act 2010 (Cth); and states and territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the Fair Trading Act 1986 (NZ) which prohibits false and misleading conduct by businesses.
81	The submitter is unaware whether any food enforcement agency has tested the lack of labelling as described in Section 1.2.1—9 (Information requirements for food for sale that is not required to bear a label), specifically subsection (3)(c) with reference to subsection (2), in a legal manner or court.	Professional Food and Pharmaceutical Services, Victoria	FSANZ does not have the legal authority to enforce the Code; it is the responsibility of the relevant Australian and New Zealand enforcement agencies to determine what action should be taken for a product that does not comply with subsection (3)(c) of Standard 1.2.1.
82	One submitter recommends clarification of the term 'fresh' as it applies to fruits and vegetables, by way of a definition or reference to a definition [in the drafting]. In the absence of criteria that delineates 'fresh', there could be confusion regarding what are the intrinsic or extrinsic physicochemical attributes of the specific fruits and vegetables that define them as fresh. The submitter refers to the NZ MPI Standard 152.02: Importation and clearance of fresh fruit and vegetables into NZ (19 Nov 2020); the ACCC Food descriptors guideline to the TPA 2006; and the USFDA Code of federal regulations title 21 Subpart F as examples of where definitions of the term 'fresh' are provided. Other submitters were of the view that the marketing and labelling of irradiated food as 'fresh' raises issues regarding false and misleading representations. Irradiated produce is intentionally and significantly	Food Safety Standards and Regulation, Health Protection Branch, Department of Health, Queensland Food Irradiation Watch/Gene Ethics Private individual	The term 'fresh' has been used in this application to clarify the types of produce items that may be permitted for irradiation. The Code does not regulate the use of 'fresh' claims made on food labels. Suppliers can voluntarily provide this kind of information on the labels of their food products, as long as the information is not false, misleading or deceptive under consumer protection legislation.

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	altered and should not be described or marketed as fresh. Food Irradiation Watch also referenced the ACCC Food Descriptors Guideline[34] in its comments on this issue. Their views were that these guidelines make it clear that 'silence' or 'omission' of information is potentially misleading.		
	Monitoring, surveillance and enforcement		
83	There is scant evidence of any monitoring of the personal or public health impacts of the consumption of irradiated produce. Indeed, 'consumption data are not available.' Therefore, suggesting that food irradiation has been proven safe – without any kind of surveillance system – is scientifically indefensible.	Food Irradiation Watch/Gene Ethics Private individual	There is a long history of safe use of ionising radiation for foodstuffs both in Australia and internationally. The outcomes of FSANZ's most recent assessment for Application A1193 indicate that there are no new public health or safety considerations that need to be addressed. Diets composed entirely of irradiated food have been consumed for protracted periods by astronauts and by patients with severe immunodeficiencies with no adverse effects. Nutrient intakes of the population are monitored over time via national nutrition surveys. Using a combination of consumption data obtained from survey respondents, and food composition data from national food composition databases, these surveys can be used to determine dietary intakes, the foods contributing to nutrient intakes and any inadequate or excess intakes of nutrients in the population. National food composition databases are compiled and updated over time, with updates focussing on commonly consumed foods that are major contributors to population nutrient intakes. National food composition databases contain the best available evidence of the nutrient content of the food supply at that point in time. There are no specific nationally representative datasets for irradiated fruit and vegetables, which may be due to their limited availability in the marketplace.
84	The application does not outline a monitoring strategy for jurisdictions to ensure that irradiation is used solely for its lawful purpose and not for prohibited purposes – to extend shelf life; to remove pathogenic microbial contamination; or to sterilize produce. The re-irradiation of produce (to deal with post irradiation contamination) is also inadequately monitored. Without a strict monitoring and enforcement regime, there are no guarantees that food will not be	Food Irradiation Watch/Gene Ethics Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Section 1.5.3—3 of the Code states the permitted uses and doses for irradiation of fruit and vegetables. The permitted doses are considered to be insufficient for microbial decontamination and they will not markedly increase shelf life. Section 1.5.3—6 (Re-irradiation of food) of the Code includes several conditions for the re-irradiation of food. The re-irradiation of produce to deal with post irradiation contamination is not one of those conditions. Monitoring and enforcement of compliance with Code requirements is the responsibility of the relevant enforcement agencies in each Australian state and

[34] Australian Competition and Consumer Commission, Food and beverage industry food descriptors guideline to the Trade Practices Act NOVEMBER 2006, p 16 https://www.accc.gov.au/system/files/Food%20descriptors%20guidelines.pdf

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	irradiated for other than what is permitted, for distributor convenience or marketing advantage.		territory and New Zealand.
85	Without stringent controls in place which require evidence of the need for use and export destination, a blanket approval could see irradiation turned into a routine practice. It is easier to just treat all items rather than those specifically identified as being transported across quarantine borders. This would lead to a much larger impact on the nutritional value of the fruits and vegetables available for consumption than has been identified in the supporting document.	Food Irradiation Watch/Gene Ethics Private individual	The application seeks to permit the use of irradiation as a voluntary phytosanitary measure for all types of fresh fruit and vegetables. This does not constitute a blanket approval; rather, in practice, only a small proportion of fresh produce available in Australia and New Zealand will be permitted to be irradiated – that which crosses quarantine borders. Even then, a proportion of the produce may continue to be treated with other permitted phytosanitary treatments. Enforcement of the use of irradiation is the responsibility of the relevant Australian and New Zealand enforcement agencies. FSANZ does not agree with the submitter's claim that it is easier to just treat all items. The processing of food by irradiation, like other food processing processes, is strictly regulated and there is no incentive for industry to use irradiation other than where it is necessary and permitted. There are additional costs associated with using irradiation as a phytosanitary treatment. Irradiated products require labelling and the process adds extra time and handling within the supply chain, including transport to and from the irradiation facility. In addition, with only one irradiation facility based in Queensland and one in Victoria, there are limits to the quantities of fresh produce that can be treated. Considering the above factors, it is unlikely that irradiation will be 'turned into a routine practice' with larger impacts on the nutritional value of fruit and vegetables available for consumption that have been identified in SD1.
86	Quality assurance and independent monitoring systems are essential to prevent misuse of irradiation, ensure good production practices, and adherence to standards. Yet quality control is left mainly to the discretion of the irradiation industry itself.	Food Irradiation Watch/Gene Ethics Steritech, Queensland Professional Food and Pharmaceutical Services, Victoria	The processing of food by irradiation is one of the heaviest regulated and audited treatments available to industry. The periodic assessment of radiation equipment and premises for compliance with standards and the maintenance of records by irradiation facilities is covered under existing state/territory or New Zealand irradiation licensing requirements. The food irradiation industry in Australia advises that facilities are audited annually by numerous organisations including federal and state agricultural departments, the Therapeutic Goods Administration (TGA) and foreign trade partners.
87	The public would likely have more confidence in the sale and consumption of irradiated food, if information was provided about the ability to detect foods which had been irradiated.	Private individual	Monitoring and enforcement of compliance with Code requirements is the responsibility of the relevant enforcement agencies in each Australian state and territory and New Zealand. Various methods exist for detection of irradiated foods. Current detection methods for irradiated food are able to detect whether a food

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			has been irradiated or not, but cannot accurately measure absorbed doses as the changes that irradiation induces in foods are minimal. However, the dose is established and controlled by accurate dosimetry and maintenance of records by irradiation facilities under the existing state/territory or New Zealand irradiation licensing requirements and maintenance of records requirements under Standard 1.5.3 of the Code. See response to no. 86 above in relation to the regulation of the food irradiation industry.
88	FSANZ has contributed to the ambiguity around what is the permitted use of irradiation, acting as a promoter by referring to its use as for 'safety' and identifying shelf life extension and the inhibition of sprouting in vegetables as positive outcomes of irradiation, even though these are not permitted uses under the Standard[35]. Commercial irradiator Steritech also claims the benefits of shelf life extension, even though this is not a permitted purpose for the irradiation of produce[36].	Food Irradiation Watch/Gene Ethics	The applicant's stated technological purpose for irradiation is as a phytosanitary measure (pest disinfestation) and it is on this basis that FSANZ conducted its technological and safety assessment. The submitter is referring to general information about irradiation provided on a FSANZ webpage, which is not related specifically to this application. The same FSANZ webpage advises that in Australia and New Zealand fruit and vegetables can only be irradiated to treat pests. The submitter is also referring to a Steritech online promotional brochure, which may also be accessible to potential international clients. For Australian and New Zealand produce destined for export to other countries, the regulations of the importing country will apply. A number of countries permit use of food irradiation for shelf life extension.
89	There is no simple, reliable and affordable test for irradiated foods and so it may be difficult for state and local authorities to monitor produce in the marketplace, to assess the dose used or to enforce the labelling requirements. Data on the background, inherent levels of radiation that may be present in produce from geographical areas should be required to ensure enforcement may be conducted. If a mandated standard cannot or will not be enforced, then should such a standard be permitted? This is in noting that FSANZ is not responsible for enforcement of food standards.	Food Irradiation Watch/Gene Ethics Private individuals Professional Food and Pharmaceutical Services, Victoria	See response to no. 87.
90	There are at least five radiolytic biomarkers available	Food Irradiation	FSANZ's scientific literature search regarding the presence of the five listed

[35] https://www.foodstandards.gov.au/consumer/foodtech/irradiation/Pages/default.aspx.
[36] https://steritech.com.au/wp-content/uploads/downloads/Steritech_Fresh_Produce_Brochure_Web.pdf.

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	to test for irradiated food – n-pentadecane, 1-hexadecene, 1,7-hexadecadiene, n-heptadecane and 8-heptadecene. They should have been widely used in the monitoring and compliance regime for A1092 and previous irradiation approvals. Yet there appears to be no data publicly available from such testing, which suggests that there has been no monitoring of compliance of the foods already approved for irradiation.	Watch/Gene Ethics	radiolytic biomarkers indicates that whilst one or more of these may be present in ham, sausages, sesame seeds, perilla seeds, shrimp, soybeans, essential oils and herbal medicines post-irradiation, there are no published reports of their presence in fresh fruit or vegetables. See responses above in relation to monitoring and enforcement.
91	Recent Failing Foods Reports, compiled from inspection and testing carried out by the Department of Agriculture, identified numerous cases of non-permitted irradiated ingredients in products, including maize flour, chillies, garlic and onions[37]. This would suggest that illegal irradiation is common and the lack of a precise and easy test makes it difficult to assess whether a product has been irradiated or not.	Food Irradiation Watch/Gene Ethics	The results noted in one Failing Food Report dated October 2018 do not, on their own, suggest that illegal irradiation is common, as claimed by the submitter. A review of more recent (2020) Failing Food Reports indicated that there were no noncompliant results for irradiation for that year. In addition, results for noncompliance in imported foods do not necessarily reflect noncompliance in domestically grown and produced foods. As mentioned at no. 84 above, FSANZ does not enforce the Code, and cannot comment on such activities undertaken by the Department of Agriculture, Water and Environment (DAWE) as the relevant enforcement agency for imported foods, other than to note that when noncompliant shipments are identified, future consignments of the food are subject to an increased rate of testing until a history of compliance is achieved.
	Freshness/Quality		
92	Many submissions included comments about the impact that irradiation may potentially have on the produce, in terms of freshness and quality and, subsequently, on those consuming the treated food. Examples of some of the comments include: - Irradiation will destroy all living enzymes. - Irradiation may affect enzyme activity/enzyme expression with consequential negative effects on human metabolism/health. - There may be as yet undiscovered phytochemicals that may be adversely affected by irradiation with consequential negative effects on human health. - Evidence shows that the natural bacteria on the skins of fresh produce are important for the health	Private individuals Ceres Natural Foods	Treatment with the appropriate doses of irradiation, within the approved dose range of 150 Gy – 1 kGy is likely to minimise any impacts on the overall freshness and quality of fruit and vegetables. Optimal dosages for specific commodities are determined through experience and experimental data. Irradiation is not proposed as an alternative to GAP and appropriate hygiene measures are still necessary to ensure that safe and suitable produce is provided to consumers. Food irradiation cannot be used to clean up already spoiled food. See also response to no. 61. There is no evidence that irradiation has a detrimental impact on human health through destruction of enzymes or beneficial bacteria.

[37] https://www.agriculture.gov.au/import/goods/food/inspection-compliance/failing-food-reports/oct2018#random-monitoring-of-food-for-compliance.

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	of the human gut biome and irradiation also kills that good bacteria. - Irradiation does not kill viruses and all bacteria and it does not remove toxins in the fruit, giving consumers a false sense of security over the handling of fruits. - Irradiation kills the goodness of fresh produce. - Food should be natural and the way it was intended to be consumed. - Irradiation kills the food.		
93	The Mango Quality Assessment Manual lists one of the causes of post-harvest lenticel discolouration as being 'Damage from irradiation used for insect disinfestation' (AMIA 2009).	Friends of the Earth NZ	Lenticel discolouration may be due to a combination of factors also including post treatment storage conditions and time of harvest. Treatment with the appropriate dose within the approved dose range of 150 Gy – 1 kGy for mangoes is likely to minimise the occurrence of any such discolouration, notwithstanding other external factors.
94	Many submissions included comments that fruit and vegetables should not be tampered with, that irradiation is a form of food tampering, and that fruit and vegetables should be available for purchase and consumption in their fresh, natural and unadulterated state. Examples of some of the comments include: - Food has to be minimally tampered with. - We have already interfered too much with the food we eat. - If the application is approved, consumers will no longer have the right to buy nutritious unadulterated food. - Consumers have the right to buy produce that is not interfered with.	Private individuals	Irradiation does not constitute a form of food tampering. The irradiation of fruit and vegetables as proposed in the application has been assessed as an appropriate and efficacious treatment and there are no public health and safety concerns associated with its use. There are already a number of existing phytosanitary treatment options from which the horticultural industry may choose, to ensure safe and suitable produce is available to consumers in Australia and New Zealand. If the application is approved, irradiation will be another such option; its use will be voluntary and based on individual business requirements. Mandatory labelling requirements for irradiated foods will enable consumers to make an informed choice.
95	Submitters, some of which may not have been aware of the National Standard for Organic and Bio-Dynamic Produce (2016) [38], queried whether foods that have been produced organically and certified organic will be required to be irradiated prior to transport to other states. The concern is that organic producers will lose their hard-earnt organic status, as no organic certifier	Private individuals Organic Industries of Australia NASAA Organic	The National Standard for Organic and Bio-Dynamic Produce (2016)[39] states: 'Irradiation is not permitted in the processing, storage or handling of products complying with this Standard'. To comply with this national standard, operators within the organic produce industry that seek to transport their produce from one quarantine region to another would refer to permitted pest control measures as outlined in that standard – irradiation is not one of those measures.

[38] https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/aqis/exporting/food/organic/national-standard-edition-3-7.pdf.
[39] https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/aqis/exporting/food/organic/national-standard-edition-3-7.pdf.

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	will allow food irradiation as a treatment for organic foods. A submitter under the impression that food irradiation would be made compulsory, was concerned that irradiation could have a significant detrimental effect on organic producers. They called for collaboration with the organic produce industry as part of implementing this measure to ensure a phytosanitary alternative is provided for organic producers.		
96	The submitter is of the view that the applicant bases most of their argument on the need to access export markets and that this reasoning is flawed. This issue is raised in the broader context of equivalence of national organic standards, in particular, the ability of Australian organic producers to access premium export markets. Broad approval of irradiation will only further undermine challenging equivalency negotiations.	Organic Industries of Australia	See response to no. 55 regarding FSANZ's assessment of the technological justification of this application. FSANZ must assess this application in accordance with the FSANZ Act. As explained in Section 6 of this report, that Act requires FSANZ to have regard to a number of matters in that assessment. These include the protection of public health and safety, which remains FSANZ's primary objective in standards development and in this assessment. As explained in this report, FSANZ's assessment, based on the best available scientific evidence, is that permitting the irradiation of fruit and vegetables in the manner sought by the application would not pose a public health and safety risk. The Act also requires FSANZ to have regard to the promotion of consistency between domestic and international food standards and to the desirability of an efficient and internationally competitive food industry. A generic approval for fruit and vegetable irradiation will bring Australian and New Zealand regulations more into line with the regulations of current and potential trading partners. This will strengthen Australia's and New Zealand's positions as international trading partners, support trade negotiations, and reduce barriers to trade. The equivalence of national organic standards is outside the scope of the application and FSANZ's area of responsibility.
	Horticultural industry		
97	A range of comments were made regarding how the use of phytosanitary irradiation will be of benefit to the horticultural industry: - The application is supported, as current treatment options are not reliably effective and can cause damage to shelf life and product quality. In the case of cold disinfestation, this is a slow process which can be detrimental to some varieties. In all,	Apple & Pear Australia Ltd PM Fresh, NSW Southern Cross Produce, New Zealand	Noted.

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	this restricts the business from supplying some markets, with the market going underserviced and prices for consumers rising. - Unlike chemical alternatives, which may remain a concern for workplace health and safety, irradiation is a feasible and ozone friendly alternative. - Phytosanitary irradiation has been shown to be one of the most reliable and commercially effective biosecurity treatments available. Irradiation also remains extremely sustainable. It is a highly automated process, with an extreme level of process control. It will help ensure a reliable supply of diverse and high quality produce. - Although the volumes of each approved crop treated remain very seasonal and make up a small percentage of total harvest, the treatment, when required, plays a critical role in the supply chain, ensuring a prosperous and sustainable fresh produce industry. - Irradiation has enabled effective market access where dosimetry has proven to be efficacious for broad spectrum pest control and maintenance of product quality. - Approval of the application will create opportunities for the industry to access a range of new markets for trade, enhance distribution, create greater access for consumers, and thus support market growth. - Generic approval of irradiation will not limit organic fruit and vegetable choices. - In terms of emergency preparedness and food security, there is already a generic irradiation treatment for almost any insect/crop combination. It is thus a viable treatment in the event of a foreign or exotic pest incursion. The inability to use irradiation as a generic treatment places the entire Australian horticultural industry at unnecessary and great risk.	Melissa's World Variety Produce, US Seeka, Fresh produce company, NZ Steritech, Queensland Momack Produce, Victoria Ontario Group, Dimbulah Queensland Australian Table Grapes Association, Victoria	

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98	The submitters requested that proposed permissions be extended to include cut flowers, particularly roses. Current approved phytosanitary treatments for import of roses (including MeBr) have their disadvantages with regards to the environment and in particular the ozone layer. A more environmentally sensitive approach to pest management would be welcomed. The X-ray phytosanitary irradiation treatment facility in Melbourne is cold chain friendly, chemical free, and ozone friendly.	Mr Fresh, Victoria Fairtrade Australia New Zealand (FANZ)	Out of scope.
99	Submitters were concerned that irradiation of fresh produce would facilitate imports of cheap and possibly over-sprayed and sub-standard irradiated food from overseas countries and this would have a negative impact on the domestic horticultural industry, significantly undermining the local primary production sector and businesses. State and Federal Government have a responsibility to protect food producers as Australia is in danger of losing food security. Submitters queried whether there had been consultation with government in this regard and, if so, what had been their response?	Food Irradiation Watch/Gene Ethics Private individuals Wiser Equity Pty Ltd Consumers SA GE Free Northland	Approval of this application will not facilitate the import of over-sprayed and sub-standard irradiated food. All imported food for human consumption must comply with the requirements of the *Imported Food Control Act 1992*, administered by DAWE, and is subject to the same requirements of the Code that cover domestically produced food. These include the requirements covering the irradiation of food (as set out in Standard 1.5.3) and those covering maximum residue limits (MRLs) of agricultural or veterinary chemicals present in a food product. In terms of consultation with government, supportive submissions have been received from a number of government agencies. These include DAWE, Biosecurity New Zealand (part of NZ MPI), the Victorian Department of Health and Human Services, the Victorian Department of Jobs, Precincts and Regions, Biosecurity Tasmania, and Department of Health Queensland. In particular, the two principle biosecurity agencies – DAWE and Biosecurity New Zealand – endorse the use of irradiation as an important quarantine measure for regulated pests. Biosecurity Tasmania endorses irradiation as a quality alternative to MeBr fumigation and use of certain insecticides that are becoming more restricted or being phased out. Numerous submissions from horticultural businesses indicate that phytosanitary irradiation can potentially benefit (as opposed to have a negative impact on) the domestic horticultural industry by allowing broader market access for domestic trade and increasing choice by businesses to use a proven quarantine treatment to eradicate fruit fly and other regulated pests. In addition, phytosanitary irradiation will be a viable treatment for crops in the event of a foreign or exotic pest incursion, which would otherwise place the Australian horticultural industry at unnecessary risk.
100	Submitters were concerned that food irradiation is	Private individuals	If this application is approved, irradiation will not be a mandatory treatment under

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	part of an industrial food production model that favours profits of large agricultural companies over people's health and livelihood. The use of food irradiation could create problems for small farmers who either do not wish to or have the infrastructure/ finance to irradiate food. If this application is approved farmers markets and other small holdings will suffer badly.		the Code. Rather, it will be only one of a number of existing phytosanitary treatment options from which the horticultural industry may choose. It will be up to individual fresh fruit and vegetable suppliers to decide on the phytosanitary treatment that is best for their particular circumstances, whilst ensuring that the produce they supply is safe and pest free. This applies to imported and domestically produced food – as well as produce destined for farmers markets – as is the current situation for produce that is already approved for irradiation.
101	Irradiation will negatively impact the value of Queensland export markets. Queensland horticultural producers will lose valuable market share if their quality produce is irradiated.	Private individuals GE Free NZ	Standard 1.5.3 of the Code applies to all states and territories in Australia and New Zealand. Therefore, if Application A1193 is approved, irradiation will be a permitted phytosanitary measure for fresh produce throughout all of Australia and New Zealand and not just Queensland. Irradiation will not be a mandatory treatment under the Code. Rather, it will be only one of a number of existing phytosanitary treatment options from which the horticultural industry may choose, depending on their individual circumstances.
102	Irradiation is a clear step away from Australia's and New Zealand's food production reputation for being clean and green.	Food Irradiation Watch/Gene Ethics	In responding to this submitter's concern it is useful to note: • Phytosanitary irradiation has already been approved for 26 fruit and vegetables, a number of which are being successfully exported from Australia to countries including Vietnam, Indonesia and the US. • New Zealand does not have a food irradiation facility and is not an exporter of irradiated produce. • Irradiation is a chemical-free treatment. • Irradiation is a viable and effective post-harvest alternative to chemical treatments, particularly in cases where such treatments have been restricted or are being phased-out. Examples include the insecticide dimethoate and the fumigant MeBr, which has potential negative effects on the environment. • At phytosanitary doses of irradiation, there is no evidence that there are reductions in quality of fresh produce. There are strict guidelines and standards for the operation of irradiation facilities, use, storage, transport and disposal of radioactive material, to ensure protection of human health and the environment, thus reducing any potential negative impact on the countries' clean and green reputation.
103	The community should invest in local farmers – there will be no need to use phytosanitary irradiation as food will not have to travel so far and will not be crossing quarantine borders.	Private individuals	The issue of investment of the local horticultural sector is not in scope. The use of phytosanitary irradiation may provide consumers, particularly those residing in states and territories that do not have a large horticultural sector, with a more secure supply of produce throughout the year and the opportunity to try imported, niche-market tropical/ exotic fruit not otherwise available domestically.

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			Not all produce crossing domestic quarantine borders requires a phytosanitary treatment.
	Harmonisation of regulations and trade		
104	The application is in line with International Standards for Phytosanitary Measures (ISPM) 18 and ISPM 28.	New Zealand Food Safety	Noted.
105	Approval of the application will bring Australia and New Zealand into line with the legislative approach taken by other countries trading in irradiated fresh fruits and vegetables. The origins of this generic approach is the 1994 guidance produced by the ICGFI (ICGFI Doc 15, Annex 2, Class 2 – fresh fruits and vegetables).	Food Irradiation Specialist of the Joint FAO/IAEA Programme of Nuclear Applications in Food and Agriculture	Noted.
106	Approval by FSANZ will not automatically allow access for the commodity to be imported into New Zealand under the Biosecurity Act 1993. MPI requires an import health standard (IHS) to be developed for each commodity prior to importation into New Zealand.	New Zealand Food Safety	Noted.
107	The applicant bases most of their argument on the need to access export markets. FSANZ's assessment on the need for irradiation should be made on the quality and safety of food, not on trade considerations and market disruption. FSANZ's assessment has shown that FSANZ has put commerce before food safety. Submitters provided a range of comments related to this issue including: - The primary orientation of FSANZ is to protect the billion dollar food export and production industry. - Providing Australians with nutritionally depleted and potentially harmful foods in order to expand interstate or overseas trade is unacceptable. - Irradiation is a produce import-enabling tool. - Food irradiation benefits only global industrial agribusiness and may facilitate access to some overseas markets. - The claimed benefits of food irradiation as a market access tool for producers should be weighed against any perceived benefits and costs	GE Free NZ Wiser Equity Pty Ltd Food Irradiation Watch/Gene Ethics Private individuals Health practitioner Consumers SA	Noted. See response to no. 96 regarding FSANZ Act requirements in assessing applications. The Act also requires FSANZ to have regard to the promotion of consistency between domestic and international food standards and to the desirability of an efficient and internationally competitive food industry. See response to no. 117 for FSANZ's position statement on how section 18 (core) objectives of the FSANZ Act are applied. Appendix 1 of this report provides a summary of specific countries' permissions for irradiated foods (focussing mainly on those in the Asia Pacific region and, as such, potential trading partners), including permissions for the irradiation of fresh fruit and vegetables as a phytosanitary measure. Of the 11 countries listed in Appendix 1, 8 have generic permissions for fresh fruit and vegetables.

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	for consumers and government. The following is a selection of comments more specifically related to harmonisation of regulations: - Access to a market can be expedited if the importing country knows that a reciprocal approval for its commodities is possible. - FSANZ justifies approving A1193 to promote consistency with other international regulations however this is misleading because while some countries have general approvals for the irradiation of fruits and vegetables many others do not. - Internationally, very few countries apply this form of food treatment, other than China and Russia. - Irradiation has not been widely adopted (e.g. The EU limits approvals to herbs and spices; Japan allows irradiation of potatoes only).		
108	The submitter states that in the prior application A1092, FSANZ makes the argument that there is a risk to market disruption if foods are not irradiated. The submitter has provided some data to indicate that this has proven to be untrue. There has been a steady economic growth of the state and industry and to regional health without having foods irradiated. In addition, the submitter notes that in the 7 years from 2012-2019, growth (as determined by GVP) has been substantial and does not support the premise that not being able to irradiate fresh fruit and vegetables is affecting the imports of these foods into New Zealand. Nor has the market or trade suffered from the lack of irradiation of these foods.	GE Free NZ	The issue of market disruption/market uptake resulting from irradiation approvals is out of scope. Application A1092 (approved in 2014) sought permission to irradiate a range of fresh fruit and vegetables. As a result of Application A1092 and subsequently Application A1115 (blueberries and raspberries), a total of 26 fruits and vegetables are currently permitted to be irradiated for a phytosanitary objective. Of these, New Zealand permits the import of irradiated capsicum, grapes, papaya, lychee (litchi), mango and tomato. Therefore, the data identified by the submitter does not, on its own, support their argument that growth in the economy, marketplace and trade has occurred in the absence of any trade in irradiated produce. There is no evidence that permitting irradiation of fruit and vegetables for phytosanitary purposes will result in a notable increase in the quantities of irradiated fruit and vegetables in Australia and New Zealand.
109	The claim that irradiation will help promote the export and import of treated fruits and vegetables is questioned as, in 2016, the IAEA reported that 70% of Queensland produce irradiated each year was sold within Australia[40].	Food Irradiation Watch/Gene Ethics	FSANZ is unable to comment on the claim made by the IAEA. If this application is approved, permissions will cover both imported and domestically produced fruit and vegetables. Irradiation will be only one of a number of existing phytosanitary treatment options and the choice of treatment

[40] https://www.iaea.org/newscenter/news/new-zealand-can-import-winter-tomatoes-thanks-to-australias-food-irradiationfacility.

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			will be up to each individual business/importer, based on an assessment of effectiveness and cost. For Australian and New Zealand produce destined for export to other countries, the regulations of the importing country will apply.
110	Trade in irradiated fruit and vegetables already occurs. This fact is not publicised and so is not widely known or understood in Australia. The whole trade is kept very quiet. Clearly deliberately so because the industry knows that consumers reject the technology when it is explained to them and so no good reason for it.	Private individual	Noted. FSANZ cannot comment on industry-initiated publicity or awareness raising initiatives, nor on industry's understanding of consumer attitudes towards food irradiation.
	Packaging		
111	There is no clear regulatory guidance in the Code on irradiated packaging or assurance that packaging will be appropriate to withstand irradiation. US regulations[41] have clear guidance on appropriate materials within the food code; irradiation in the production, processing and handling of food and Australia ought to follow suit.	Food Irradiation Watch/Gene Ethics	There are packaging regulations in the Code and related legislation in New Zealand and in state/territory food laws. For Australia, Standard 3.2.2 – Food Safety Practices and General Requirements has requirements pertaining to food packaging. Standard 3.2.2 requires that food businesses (including manufacturers, importers and retailers) must only use packaging that is fit for its intended use and only use material that is not likely to cause food contamination. For New Zealand, similar requirements are set out in the New Zealand Food Act 2014. The regulations apply to all food packaging materials including those that are intended to be irradiated.
	Cost/benefit		
112	Submitters raised several issues that relate to FSANZ's consideration of costs and benefits, including: • The public will be exposed to further risks, costs and hazards. • Irradiation of fresh fruit and vegetables will increase costs [to consumers]. • Approving this application will detract overseas tourists, as their food regulations are more stringent than those in Australia/New Zealand. • Analysis of all the other alternative phytosanitary	Private individuals Ceres Natural Foods	The application does not require the irradiation of all fruit and vegetables, rather it provides a safe post-harvest phytosanitary treatment option for industry to use. A cost benefit analysis of all the other alternative phytosanitary measures is not necessary as use of irradiation is voluntary. There are already a number of existing phytosanitary treatments permitted for use by the horticultural industry, to ensure safe and suitable produce is available to consumers in Australia and New Zealand. If the application is approved, due to the voluntary nature of the permission, the horticultural industry will only use irradiation where they believe a net benefit exists.

[41] https://www.ecfr.gov/cgi-bin/textidx?SID=a039ae3770875b2505085a2214537653&mc=true&node=pt21.3.179&rgn=div5#se21.3.179_126.

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	hasn't been undertaken. • Analysis of the benefit of food irradiation.		Mandatory labelling of irradiated fruits and vegetables provides information to enable consumers to make informed choices.
113	Any treatment to human food that decreases the nutritional value of the food should require further investigation to properly compare the costs and benefits.	Private individual	Multiple independent assessments were conducted by FSANZ, including the current assessment and others listed in Table 1 of SD1. FSANZ concluded that based on the available evidence that the effect of irradiation on the micronutrient intake of fruit and vegetables is likely to be low.
114	Irradiation of all produce will result in millions of people being more susceptible to chronic illnesses and this will be a burden on the economy (note no supporting evidence).	Private individual	As part of their application, the applicant was required to provide FSANZ with evidence that supports the safety and nutritional adequacy of irradiated produce. Whilst this information is useful, FSANZ did not rely solely on the information submitted by the applicant. As stated above, FSANZ has conducted its own comprehensive assessment of the scientific literature for the current application, that builds upon earlier assessments conducted as part of multiple previous applications. See also response to no. 112.
	FSANZ's communications on irradiation		
115	FSANZ should seek to communicate with the horticultural sector about the proposed new permission and consumers, noting there may be an increase in irradiated foods in the market.	Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	The available evidence is that permitting irradiation of fresh fruit and vegetables for phytosanitary purposes will not result in a notable increase in the amount of irradiated food in the community's diet. No evidence was provided by submitters to the contrary. FSANZ will continue to look for ways to raise awareness and understanding of the application and food irradiation more broadly.
116	The TGA permits irradiation as a decontamination treatment and requires monitoring of its potential adverse impacts[42]. Biosecurity Australia permits irradiation for quarantine purposes yet also notes that irradiation does affect certain vitamins and other nutrients and does produce peroxides and other radiolytic by-products, some of which may be toxic and/or carcinogenic, and that these effects are dose related[43]. Rather than looking for ways to communicate the 'safety and benefits' of irradiation, FSANZ should demonstrate the same candour when	Food Irradiation Watch/Gene Ethics	In five separate applications to amend the Code, FSANZ has undertaken independent risk assessments of the effects of irradiation on the nutritional impact of irradiation on individual or groups of fruit and vegetables as outlined in Table 1 of SD1 and available on our website. In 2014 FSANZ conducted and made public on its website a report on the nutritional impact of phytosanitary irradiation on a range of fruit and vegetables. For the purposes of this application FSANZ undertook a further assessment of the nutritional impact of fruit and vegetables which is available in Section 4 of SD1. The nutrition risk assessment conclusion (Section 4.4) and risk characterisation (Section 6) of SD1 provides a comprehensive description of the

[42] Australian Government, Department of Health, Therapeutic Goods Authority, Australian regulatory guidelines, Information required in an evaluation of a substance for use in listed medicines, Version 1.0, May 2020, p14.
[43] https://www.agriculture.gov.au/biosecurity/risk-analysis/animal/gamma-irradiation/questions-and-answers.

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	representing the public nutrition, health and safety issues around irradiation of food.		findings of the risk assessment. FSANZ has also developed a consumer information page which discusses the safety, quality and labelling aspects for irradiated foods in Australia and New Zealand. On the basis of risk assessments conducted by FSANZ and by other regulatory agencies, no monitoring of effects of radiolytic products is considered necessary or appropriate. Peroxides and some other radiolytic products are extremely reactive and therefore very short-lived in irradiated foods, and would not still be present at time of sale. With the exception of 2-ACBs, radiolytic products are also generated by other thermal processes including cooking. 2-ACBs are of low toxicity and levels of 2-ACBs in irradiated fruits and vegetables are minimal to negligible, because they are formed when lipids are irradiated. While furan is considered a possible carcinogen, the level of furan in irradiated fruits and vegetables is very low compared to the levels of furan in other foods such as coffee and baked goods. Please see the Hazard Assessment section of SD1.
	FSANZ Act issues		
117	Submitters commented that our conclusions are not consistent with the three core objectives of the FSANZ Act.	Private individuals	How FSANZ meets the objectives of the FSANZ Act 1991 is addressed in Section 6.3 of this report. FSANZ also provides a position statement explaining how we apply the three section 18 (core) objectives of the FSANZ Act to the development of food standards (link below). There are no aspects in Application A1193 where FSANZ has not fulfilled its role and obligations according to this statement. https://www.foodstandards.gov.au/about/Pages/default.aspx
	The application/applicant		
118	There is concern at the use of Schedule 22 (the scope of the application includes all those fresh fruits and vegetables presently described within Schedule 22 of the Code), noting Schedule 22's main application within the Code relates to Australia-only maximum residue limits (MRLs). These 'multipurpose' provisions should be stand-alone to avoid confusion and improve transparency of application.	New Zealand Food and Grocery Council	This issue has been raised by NZFGC and responded to and addressed by FSANZ in previous applications and proposals. See, for example, Application A1163 – Food irradiation definition of herbs and spices. NZFGC has not provided, and FSANZ has not located, any evidence that would warrant a change in FSANZ's stated position on this issue to date. As previously stated: • The fact that a law or a Standard exists for one purpose does not mean that that law or Standard, or a list in one part of it, cannot be referenced and used for and by another law or Standard. This is accepted and normal drafting and legislative practice. • Schedule 22 and its precursor has been referenced by the Irradiation

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			Standard since 2001. The purpose statement in section 1.4.2—2 cannot of itself change that fact or the legal effect of section 1.5.3—3 and the definition in subsection 1.5.3—3(2). • In any event, the proposed variation for Schedule 22 itself makes clear that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of subsection 1.5.3—3(2). See Note 1 of Schedule 22. • No evidence has been presented that the proposed references in section 1.5.3—3 to two small parts of Schedule 22 will in fact create confusion or reduce transparency of application.
119	The submitter is concerned that one of the individuals involved in the preparation of the application had/has a connection to the FAO/IAEA/WHO ICGFI (and, through this, the IAEA) and that the thrust of A1193 is very much in line with the ICGFI agenda and goal.	Friends of the Earth NZ	Subsection 22(1) of the FSANZ Act states that *'a body or person may apply to the Authority for the development of a food regulatory measure or the variation of a food regulatory measure'*. The FSANZ website states that *'anyone can apply to change the Code'*. There are no restrictions as to who may/may not apply to change the Code or may be otherwise involved in the preparation of an application. Each application is assessed independently by FSANZ and in accordance with the requirements of the FSANZ Act.
120	The Queensland Government has a clear conflict of interest by being both the applicant for A1193 and having two representatives, namely the Hons Yvette D'Ath and Mark Furner, on the Forum, being one of the final arbiters of the decision on its own application.	Private individuals	This issue – which relates to the Australia and New Zealand Ministerial Forum on Food Regulation (now the Food Ministers' Meeting[44]) – is out of scope. As explained in this report, FSANZ made its own independent and evidence based assessment of the application in accordance with the FSANZ Act.
121	The submitter is of the opinion that one of the parties involved in the preparation of the application belongs to an entity that does not appear to be a legally incorporated entity.	Friends of the Earth NZ	The FSANZ Act does not restrict the ability to lodge an application under that Act to incorporated entities. The applicant in this case is the Queensland Government represented by the Queensland Department of Agriculture and Fisheries.
122	Developments since 1973 regarding the use of irradiation in New Zealand were outlined in the submission, and the submitter is concerned that relevant matters were left out of the application. For example, as early as 1973 (and revised 1984) NZ had food regulations that prohibited the sale of any food that was treated by ionizing radiation, unless the Minister of Health had approved the treatment.	Friends of the Earth NZ	FSANZ cannot comment on the applicant's decision to include/ exclude certain information from the application. At any stage during the assessment, if FSANZ decides that it needs additional information to undertake its assessment, FSANZ may request that information from the applicant, in accordance with the requirements of the FSANZ Act (Section 108).
123	The submitter disagrees with the statement on page 58 of the application that there are no examples	Friends of the Earth NZ	FSANZ evaluates the information provided in an application as part of its independent assessment. FSANZ is not responsible for inaccuracies in

[44] As of 12 February 2021, the Forum will be known as the 'Food Ministers' Meeting'.

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	where products have been withdrawn from the market because they had been irradiated, citing illegally irradiated chives withdrawn in New Zealand, irradiated cat foods withdrawn in Australia and irradiated shrimp/prawns withdrawn in Britain as examples. The submitter also disagrees with claims made in the application that there has been no negative reaction to 15 years of irradiated sales of mangoes in New Zealand and cites three New Zealand Herald news articles: 'Zapped mangoes break out in blotches', 'Australian irradiated fruit found unmarked in stores', and 'How do you know fresh mango is irradiated?' etc.		information provided, particularly that which comes from a third party source. The submitter is referring to statements in the application under the heading 'Consumer Acceptance'. Regarding the applicant's first statement, in the cases cited by the submitter, the products were withdrawn from the market due to compliance and safety issues and not due to a lack of consumer acceptance. Regarding the applicant's second statement, the first New Zealand Herald article referenced by the submitter (2005) refers to blemishes present on imported irradiated mangoes, however the cause of these blemishes was not identified. The second article (2006) refers to a batch of unlabelled produce identified and reported by Friends of the Earth NZ and does not identify a lack of consumer acceptance. The third article could not be located.
124	The submitter is concerned that this application will set a precedent for other states to follow suit.	Friends of the Earth NZ	The submitter's concern is unwarranted. Standard 1.5.3 of the Code applies to all states and territories in Australia and New Zealand. Therefore, if Application A1193 is approved, irradiation will be a permitted phytosanitary measure for fresh produce throughout all of Australia and New Zealand.
125	Organic and bio-dynamically produced food should be exempted from this application.	Friends of the Earth NZ	See response to no. 95.
	Consumer choice and acceptance		
126	One submitter stated that continuing sales of irradiated produce in New Zealand and Australia is evidence that consumer purchasing is not negatively impacted. Another submitter noted that for years there have been opinions that consumers would not eat irradiated table grapes; in the submitter's opinion this is unfounded.	Steritech, Queensland Australian Table Grapes Association, Victoria	Noted.
127	Submitters were of the view that consumers should be given the choice as to whether or not they purchase irradiated foods. Some submitters expressed these views under the incorrect assumption that irradiation would be mandatory for all fresh produce and, as such, non-irradiated produce would no longer be available. In this context, several submitters were of the view that	Private individuals	Refer to response for no. 112.

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	the application was against human rights as it took away peoples' freedom of choice. Others stated that they did not want government agencies making decisions on their behalf. A submitter commented that there still needs to be a wide selection of non-irradiated foods available, and that irradiated foods need to be clearly marked. Another submitter commented that for those consumers that don't want to eat irradiated produce, this application would unfairly favour those who can afford organic.		
128	A review of actual purchase behaviour suggests that while a fraction of the public will not buy irradiated food, a much larger fraction will (Roberts and Henon 2015). It is unclear whether this research addressed people actually buying irradiated food or saying they would.	Consumers SA	The submission from Consumers SA attributes this quote to FSANZ, however its source is the Executive Summary and Section 5.2 of the application. Roberts and Henon (2015) is a short narrative review drawing on international experience and a case study of imported irradiated food from Australia to New Zealand. The review does not provide methodological details of the studies reviewed. They draw on the continuing market for irradiated products as evidence of actual consumer behaviour.
	Public awareness/opinion		
129	FSANZ has not investigated Australian public resistance to irradiation and is forcing this upon consumers. There is no reliable evidence that the Australian and New Zealand public are aware of, or will consent to, the widespread irradiation of fresh produce.	Private individuals	FSANZ has undertaken a comprehensive round of public consultation as part of this application and as required by the FSANZ Act. Approval of the application will not force irradiation upon consumers. As explained in the Approval Report: irradiation will remain voluntary and only a small proportion of fruit and vegetables available in Australian and New Zealand will likely be irradiated. Labelling requirements will continue to apply to enable consumers to make an informed choice. Consumers are likely to have limited exposure to irradiated food and labelling given the low numbers of irradiated food in the marketplace. This may also mean that consumer awareness and understanding of the food irradiation process and labelling requirements is low. See FSANZ's 2016 review of the mandatory labelling of irradiated food. FSANZ will continue to look for ways to raise awareness and understanding of the application and food irradiation more broadly.

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			An experimental study found that labelling information, coupled with education, can positively influence the acceptability of irradiated foods (refer to Supporting Document 2 to the Review report). FSANZ has therefore developed a web-based education campaign to help people understand what food irradiation is and FSANZ's role in ensuring its safety. FSANZ will continue to explore ways to inform and raise awareness within the community about food irradiation.
130	Many in the general public are not aware of the foods already approved for irradiation and likely not aware of the proposed changes. As it is not a well-known, understood or accepted practice they are unwittingly participating in what amounts to a completely uncontrolled experiment on the impacts on the human body of introducing wide-scale irradiated foods to the Australian fresh fruit and vegetable supply. Surveys have shown that even when educated, public opinion is negative towards irradiation and it is not a preferred treatment. For example, market research was conducted for an article that appeared in The Land, '*The survey results showed that even when informed, irradiation was not the preferred treatment method among consumers.'*	Private individual	Refer to response for no. 129 above. Use of irradiation will be voluntary and other phytosanitary treatments will continue to be available.
131	Other comments regarding consumers' views regarding the technology included: - The expansion of the use of irradiation is not welcomed by consumers, as it is far from the clean technology that proponents claim it to be. - Opposition to irradiation has been minimised. There has been in the past strong opposition and public opinion should be facilitated. If not, public confidence in the food industry will be eroded. - More up to date research should be carried out assessing the public's attitude towards irradiated produce before this application is progressed further. - There needs to be more real public discussion about food irradiation.	Private individuals Consumers SA	Refer to response for no. 129 above.
132	General public may remain vehemently opposed to food irradiation, largely because the industry has	Private individual	Refer to response for no. 129 above.

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	made little or no effort to educate the public on its efficacy and safety. Risk of media discovering that the public has unwittingly been consuming irradiated food because of inadequate legislation, inadequate monitoring or inadequate enforcement, could result in a significant backlash against the use of this extremely useful technology.		
133	If you continue with this application which is not founded on evidence based research, then I would like to warn you that you will undergo an immense amount of public backlash, especially when health effects become apparent, which from the animal studies is sooner than one would expect or hope.	Private individual	FSANZ has conducted a comprehensive assessment of the safety and technological justification of irradiation for this purpose. The evidence demonstrates that irradiation is an appropriate and efficacious phytosanitary treatment for regulated pests, including fruit fly, at the proposed dose range. See also response for no. 129 above.
	FSANZ's regulatory/standards management processes		
134	FSANZ is doing a second-rate job of managing the regulatory process.	Food Irradiation Watch/Gene Ethics	Noted. See response to no. 117.
135	Comments on the decision from *Gene Ethics Pty Ltd v Food Standards Australia New Zealand* [2012] FCA 1137 – that FSANZ had satisfied its statutory obligations, but it had failed to adhere to 'the spirit of the Act.' The misleading information related to what was easily viewable and accessible on FSANZ's webpage.	Food Irradiation Watch/Gene Ethics	Noted. See response to no. 117 on how FSANZ meets the objectives of the FSANZ Act. The Gene Ethics Pty Ltd decision found that the public notice FSANZ gave was legally valid and complied with the requirements imposed by s 31(2) of the FSANZ Act. The court in that case commented that the title 'Application A1038 – Irradiation of Persimmons', without more to identify the draft variation had the potential to mislead readers. FSANZ has since updated procedures to ensure that any public notice and associated documentation of an application is an accurate reflection of what is being varied in the Code – which is the case for this application.
136	Public notice requirements are intended to promote accountability and transparency in the regulatory framework. FSANZ has failed to transparently provide timely information to allow full public engagement. FSANZ did not notify the public that the applicant had opted to pay a fee to fast-track the assessment process. Published documents on A1193 advising that the public consultation period was scheduled for April 2021 were not updated. FSANZ is required to update the public of such timetable changes but claims that altering the dates in its Work Plan is sufficient notice to inform the public. FSANZ misled	Food Irradiation Watch/Gene Ethics Private individuals	Public notice given by FSANZ was legally valid and complied with the requirements imposed by the FSANZ Act. FSANZ received the application on 6 November 2019 and, following an administrative assessment, FSANZ accepted the application on 27 November 2019. FSANZ's acceptance of the application was publicly notified through FSANZ Notification Circular 107/20 dated 7 January 2020, in line with the requirements of subsection 28(2) of the FSANZ Act. As part of the notification, FSANZ published its administrative assessment report including a proposed timeframe for assessment. The proposed timeframe is an indicative timeline determined during the administrative assessment. The waiting period for starting the application is approximately 9-12 months. At the time the administrative

No.	Issue	Raised by	FSANZ response
	the public when it failed to publish enough information so the interested public could fully engage with the consultation process. FSANZ did not: • divulge the expedited time when it re-announced the application • provide any information on the A1193 webpage to show the timeframe had changed • reference or link to the Work Plan, the only place that updated information was posted. By changing the date of public consultation, unannounced, FSANZ has limited the scope of possible community engagement beyond FSANZ's networks, disadvantaged the community it is meant to protect and represent, and thus failed to provide opportunity for the robust community conversations required in a functioning democracy. Following the granting of a 2-week extension for receipt of submissions FSANZ failed to update its Work Plan and the A1193 webpage in a timely manner. The FSANZ Work Plan should be continuously updated and linked to application webpages in a prominent and timely way. FSANZ's notification processes fail to support or facilitate public engagement and must be overhauled to ensure that they do so.		assessment was published, the assessment of the application was nominally due to commence late-November 2020 and the public comment period (or Call for Submissions period) was nominally due to commence in early-April 2021. At any stage, an applicant can choose to pay a fee to bring forward the start date of the assessment of their application and, subsequently, the public comment period. This is what occurred in this case. Fees were received (and the assessment commenced) on 12 May 2020 (rather than in late-November 2020). The application was re-notified via FSANZ Notification Circular 122/20 dated 15 May 2020. The public comment period was subsequently also brought forward – to 30 October 2020 (from early-April 2021). The public comment period is typically six weeks in duration. In this instance, the public comment period was notified via FSANZ Notification Circular 140/20 dated 30 October 2020. As stated in Section 5.1 of this report, consultation is a key part of FSANZ's standards development processes. The Call for Submissions itself was notified via the FSANZ notification circular, a media release, and social media (over 43,000 Facebook followers and 2,500 Instagram followers), and FSANZ Food Standards News (with 7,600 subscribers, including organisations such as Food Irradiation Watch, Friends of the Earth and Gene Ethics). The public comment period was due to finish on 11 December 2020. However, in response to a request by submitters, it was extended by two weeks, to 24 December 2020. The extension was notified via FSANZ Notification Circular 144/20 (11 December 2020). Updates to timelines for this and all applications and proposals are notified in the publically available FSANZ Work Plan. This is the key document regarding expected timetables for applications and proposals and is frequently updated. The Work Plan was updated on 10 January 2020 following acceptance of the application, 18 May 2020 upon commencement of the assessment of the application and 23 December 2020 following the extension to the public comment period. FSANZ also notes the following: • The initial period given for public consultation was six weeks. This period has been the norm for FSANZ public consultation to date, including during the Covid pandemic. • Extensive public notice was given in both New Zealand and Australia of the

No.	Issue	Raised by	FSANZ response
			Call for Submissions and the relevant dates for public comment. • The A1193 eight week period for public consultation did not occur over a period with major public holidays or the like. The Call for Submissions was issued on 30 October 2020 – eight weeks before Christmas. • The opportunity for anyone who was interested to request an extension of time to make submission was clearly notified. • Submitters had the option of asking to lodge late submissions or providing comments after the period for public submissions had closed. That option was also clearly explained.
137	Submitters expressed concern about the timing and expeditious nature of this application, with submitters questioning why it was being "rushed through" at a time the general public was dealing with a pandemic, climate emergency and potential bushfire catastrophe. There was the anecdotal view that people are genuinely engaged and would like to participate in the submission process if given adequate opportunity to do so. In addition, submitters suggested that the consultation period was deliberately set to coincide with the pre-Christmas rush so as to minimise public awareness and the number of submissions. This was in noting that the '*public at large has exhibited distrust and opposition to irradiation, and likely would not give consent'.* An extension of the submission date and additional advertising and sharing of the application to the broader Australian public would be a most proactive and positive action on such an important matter.	Private individuals Health practitioners Consumers SA	The application was not "rushed through". The Call for Submissions was issued and publically notified on 30 October 2020 – eight weeks before Christmas, and any "pre-Christmas rush". In terms of public awareness, the Call for Submissions was the subject of extensive public notification. See FSANZ's response to no. 136 above. The application was assessed in accordance with the FSANZ Act. It requires FSANZ to assess each accepted application in accordance with that Act and within the timeframes set by that Act. The Act also provides that, where an applicant chooses to pay the prescribed application fee, assessment of the application must commence on the day that fee is received by FSANZ. This was the case with Application A1193. FSANZ did not have a discretion to defer or delay that assessment. The timeframe set by the Act for Application A1193 (via General Procedure Level 5) was 9 months. This included a number of statutory major milestones, as set out in the publically available FSANZ Work Plan. To complete assessment of this application within this required timeframe, an eight week public comment period was provided. A period of six weeks is typical for most applications. See also the response to no. 136 above for further details regarding the extension to the public comment period.
138	Although the submitter has long been a subscriber to FSANZ Notifications, they did not receive the notification about A1193. The Standards Management Officer was unable to explain what had happened or	Friends of the Earth NZ	FSANZ has issued a number of FSANZ Notification Circulars relating to this application including: Notification Circular 107/20 (7 January 2020), 122/20 (15 May 2020), 140/20 (30 October 2020) and 144/20 (11 December 2020). FSANZ was unable to identify the source of the issue described by this

No.	Issue	Raised by	FSANZ response
	confirm that the submitter had been sent the notification. The slight extension provided was appreciated, but the timing resulted in a very compromised submission.		submitter, nor has it received complaints from other entities regarding problems with the distribution and receipt of FSANZ Notification Circulars.
139	Contrary to correct statutory and regulatory approach, this application seeks regulatory inclusion to irradiate ALL fresh fruit and vegetables and only vaguely refers to some of those to which irradiation may or may not apply. Rather, the necessary and correct statutory and regulatory approach would be to only specify those products to which the regulations apply. The applicant has failed to do this.	Friends of the Earth NZ	Noted. FSANZ does not share these views. Application A1193 seeks permission to use irradiation as a phytosanitary measure (pest disinfestation) for 'specific products' – *all* types of fresh fruit and vegetables, excluding dried pulses, legumes, nuts, or seeds. This is reflected in the approved variation which outlines that fruit and vegetables includes (but is not limited to) a fruit and vegetable described in Schedule 22, with the exceptions. Any proposed changes to the Code, including an expansion to the permitted uses of irradiation, would require a new application/proposal demonstrating safety and including adequate technological justification. Each application is assessed on its own merits using internationally recognised risk analysis processes and the best available evidence.
140	In some ways, this application is perhaps only a step away from a possible following application to amend Standard 1.5.3 to include irradiation of all foods.	Friends of the Earth NZ	Noted. This is speculative and out of scope for this application. Any such future application would have to be assessed in accordance with the FSANZ Act.
141	It seems that the process of decision making on this application lacks a degree of independence that does not fill the submitter with confidence and trust that an unbiased decision will be made based on rigorous research and cost benefit analysis.	Private individuals	Noted. FSANZ does not share this view. FSANZ assessed this Act in accordance with the FSANZ Act.
142	Submitter finds it offensive that as an elected member, purported to do 'good', [FSANZ] makes decisions about commercial food longevity at the expense of their and their children's health.	Private individuals	Noted. FSANZ does not share this view. FSANZ assessed this Act in accordance with the FSANZ Act The reasons for its decision were explained in the Call for Submissions and are explained in this report. These include its evidence based risk assessment that there are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy. Use of irradiation will be permitted for a phytosanitary purpose only, not for shelf life extension. The permitted doses are considered to be insufficient to markedly increase shelf life of fresh produce.

No.	Issue	Raised by	FSANZ response
	Liability		
143	The application is highly controversial and unwise, scientifically and legally. It is misguided at best, reckless at worst. It is an ill-informed decision by government – government systems are looking to approve this application and so it can't be about health.	Private individuals	FSANZ's assessment, based on the best available scientific evidence, is that irradiation of fruit and vegetables in the manner proposed does not pose any public health and safety concerns. That assessment was conducted in accordance with and complied with the FSANZ Act. Irradiation has been used since the late 1950s and is one of the most extensively studied methods of food processing. The safety of irradiated foods has been evaluated by international scientific bodies and regulatory agencies in other countries, as well as independently by FSANZ. FSANZ assessments have concluded that phytosanitary irradiation is technologically justified and effective in achieving its stated purpose, and that there are no public health and safety concerns
144	A number of submitters raised concerns regarding the liability of the government (including the Queensland government) and FSANZ in relation to any long-term consequences for the public's health. Just because the government has the power to implement such measures does not excuse its duty of care or any subsequent gross negligence. The legal implications of rendering people chronically disabled would be too costly to settle and it is important to consider the lawsuits and inevitable class-actions brought to bear on those who will be found to have pushed this proposed technology onto an entire nation. Its use creates and puts upon the government and consumers cost externalities associated with healthcare impacts from nutritional depletion, allergenicity, and other identified and yet to be identified health and existential risks. The onus is on those proposing the technology to prove beyond any reasonable doubt that such an intervention is safe by studies – replicated by non-industry scientists. There was also a question of conflict of interest, specifically, who is behind the international irradiation association and has it donated any funds to the current government, even if only for 'research'?	Private individuals Health practitioner Wiser Equity Pty Ltd	Noted. See response to no. 143.
145	Irradiation will increase the profits of large agricultural and pharmaceutical companies and there is a conflict	Private individual	FSANZ is an independent authority who takes its responsibility very seriously, with an independent Board that is the decision maker. Its processes are open

No.	Issue	Raised by	FSANZ response
	of interest and corporate influence in this application. The community expects FSANZ to protect them and be aware of the corruption affecting public health and FSANZ should not assume that it will not be held accountable. FSANZ exists to serve the public and not big business or the economy.		and transparent. It has assessed the best available science to complete a rigorous and independent risk assessment which has concluded that there are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy (see SD1).
	General support		
146	Supportive of submission provided by Biosecurity Tasmania.	Tasmanian Farmers & Graziers Association	Noted.
147	It is estimated that the global trade of products irradiated for a phytosanitary purpose will reach 50,000 tons in 2020. Though not a panacea, irradiation has unique advantages to provide consumers with premium quality fresh produce. The FSANZ proposal is supported noting that in 1980 a Joint WHO/FAO/IAEA Expert Committee on Food Irradiation declared irradiated food safe and wholesome (WHO Technical Report Series no. 659 – Geneva, 1981) and an expected outcome of this would be that it would no longer be necessary to assess the safety and nutritional adequacy of any food class product by product. It is also noted that the same type of clearance has been given in other countries, including the US.	International Irradiation Association (NGO)	Noted.

Attachment 2.1 to Appendix 2: FSANZ responses to studies and articles cited by submitters

(a) Studies cited in the article 'Bad Taste: The Disturbing Truth About the World Health Organization's Endorsement of Food Irradiation'

Issue: This article raises concerns about the safety of food irradiation, based on a number of studies.

Reference: https://www.citizen.org/wp-content/uploads/badtaste.pdf (2002)

FSANZ response: FSANZ has reviewed all those studies and determined that all have significant limitations that limit their regulatory utility. For example, the results have not been interpreted correctly; the radiation dose was very high and not relevant to the current application; the test article was not fruit or vegetables; or the model system is not relevant to mammals.

- Some of the studies cited concluded that irradiation did not have negative effects on the measured parameters, including those of Poling et al. (1955); Tinsley et al. (1970); Renner (1977); and Renner et al. (1982).

- A suite of studies by Vijayalaxmi and co-authors (Vijayalaxmi 1976; Vijayalaxmi and Sadasivan 1975; Vijayalaxmi and Rao 1976; and Vijayalaxmi 1978) were cited by the article. The Indian Ministry of Health (1987) and WHO (1994) concluded neither the design or the results were adequate to demonstrate the claimed effects (Hansen 2004 https://core.ac.uk/download/pdf/12514258.pdf).

- Several studies are considered not relevant to the current application because they used doses of radiation in excess of the maximum dose proposed in the current application. Anderson et al. (1981) used ≥ 1 megarad, which is ≥ 10 kGy. Moutschen-Dahmen et al. (1970) and Bugyaki et al. (1968) used 5 megarads, and Lofroth et al. (1966a) used 2 to 9 megarads.

- Four studies are not relevant to the current application because the irradiated material was animal-derived rather than a fruit or vegetable. The study by Reichelt et al. (1972) concerns irradiation of milk powder while that of Raltech Scientific Services Inc. (1979) concerns irradiated chicken. The studies by Metta et al. (1959) and Mellette et al. (1960) concern irradiated beef and the authors of both papers clearly identify the reason for haemorrhagic illness in the test rats as being due to vitamin K deficiency rather than any radiolytic product. Mellette and Leone further remarked that 'non-irradiated diets may cause the same disease due to the same deficiency'.

- In a number of studies the test system was not a mammal and the adverse effects cannot be replicated in mammals (Thayer et al. 1987)[45]. These studies include those of Swaminathan et al. (1963); Rinehart and Ratty (1965); Rinehart and Ratty (1967); and Raltech Scientific Services Inc. (1979). Kevasan and Swaminathan (1971) used microorganisms and insects as test systems; again, these are not meaningful models of human toxicity.

  Mutagenicity assays used by Johnson-Arthur et al. (1971) and recommended by Schubert (1969) have since been abandoned as unreliable. Schubert (1969) further cited evidence that has since been shown to be not reproducible, and raised concerns around substances that have since been shown to be not of concern. It is noteworthy that Schubert's paper was presented at a meeting of the Joint FAO/IAEA/WHO Expert Committee on Irradiated Food, an organisation that has reached the conclusion that irradiated food is safe to consume.

- FSANZ notes that in the study of irradiated rodent diets conducted by Anderson et al. (1981), adverse effects were observed in association with only one of five rodent diets irradiated with ≥ 1 megarad (10 or more kGy). FSANZ also notes that numerous irradiated rodent diets are commercially available and rodent models of severe immunodeficiency have been maintained on them for many generations.

[45] Thayer et al. (1987) Toxicology Studies of Irradiation-Sterilized Chicken. Journal of Food Protection 50 (4): 278–288.

- Only one reference cited by the article, the FDA report by Spiher (1968) could not be located for review. However FSANZ notes that the current position of the US FDA is supportive of food irradiation, see https://www.fda.gov/food/irradiation-food-packaging/overview-irradiation-food-and-packaging.

(b) Studies cited in the 2003 review of multiple studies examining the effects of irradiated food on human and animal health

Issue: Submitter has cited a 2003 overview of multiple studies examining the effects of irradiated food on humans and animals.

Reference: Questioning Food Irradiation: A History of Research into the Safety of Irradiated Foods,' Public Citizen, Critical Mass Energy and Environment Program Washington D.C. April 2003.

FSANZ response: The 2003 article does not provide any credible evidence but relies on studies that are incorrect, not relevant to the current application, have been misrepresented in the article, or actually support irradiation. FSANZ's specific comments on the research cited in this review are summarised below.

- A number of the studies are misrepresented as showing adverse effects of irradiation when in fact the study authors concluded that irradiation did no harm. These include the studies of Luckey et al. (1955); Tinsley et al. (1970); Renner (1977); and Renner et al. (1982). The findings of De et al. (1969) have been misrepresented as showing evidence that an irradiated diet leads to excretion of radiation. As part of the study, the rats were intentionally fed sucrose labelled with a radioactive tracer (carbon-14) and the paper makes it very clear that the detected radioactivity came from that tracer. The authors also state 'Assessed by various parameters, no deleterious effects could be observed in rats fed the irradiated sucrose solution for a period of 8 weeks.'
- Attempts to replicate the results reported by Bhaskaram and Sadasivan (1975) in experimental animals (George et al. 1976)[46] and in humans have not been successful (Truswell 1987)[47]. Malnutrition has been shown to cause a significant increase in the frequency of chromosomal abnormalities in children (Armendares et al. 1971[48] and Mutchinick et al. 1979[49]). It is therefore unlikely that the chromosomal defects in the children were due to the wheat, and most likely that they reflected malnutrition.
- Several studies concerned irradiation of animal products rather than fruit or vegetables, and are therefore not relevant to this application. These include those of Poling et al. (1955); Metta et al. (1955); Mellette and Leone (1960); Plough et al. (1957); Reichelt et al. (1972); and Raltech (1979). Radiation destroying vitamin E (DaCosta and Levenson 1956; and Reichelt 1972) is of minor relevance only because fruit and vegetables are not significant dietary sources of this nutrient.
- Some of the cited references, including Crone et al. (1992); Stevenson (1994); Delincee and Pool-Zobel (1998); Marchioni et al. (2001); Delincee et al. (1998, 2002); and Burnouf et al. (2001) concern 2-acylcyclobutanones, which are discussed in the safety assessment for this application and earlier applications considered by FSANZ. Radiolytic products found in the study of the Life Sciences Research Office (1979) are also discussed in the SD1 of this and earlier applications. Levels are negligible and the compounds are also found in food that has not been irradiated.
- With regard to the studies by Vijayalaxmi (1976); Vijayalaxmi and Sadasivan (1975); Vijayalaxmi and Rao (1976); Vijayalaxmi (1978); the Indian Ministry of Health (1987); and WHO (1994) concluded neither the design or the results were adequate to demonstrate the claimed effects (Hansen 2004 https://core.ac.uk/download/pdf/12514258.pdf).
- Two studies showed changes that have been incorrectly interpreted as 'health problems'. Excretion of indophenol-reducing substances, reported by Bierman et al. (1958) is not a 'health problem' and nor is the increased haemoglobin reported by Jaarma (1967). Other findings in the very old doctoral thesis of Jaarma (1967) have not been replicated in subsequent studies.
- Several studies are not relevant because the radiation dose used in the studies was substantially higher than the proposed maximum in the current application. These include Bugyaki et al. (1968) (dose of 5 megarad = 50 kGy); Moutschen-Dahmen et al. (1970) (dose of 5 megarads = 50 kGy);

[46] George et al. (1976) Frequency of polyploidy cells in the bone marrow of rats fed irradiated wheat. Food and Cosmetics Toxicology 14: 289-291.
[47] Truswell (1987) Food Irradiation British Medical Journal 294(6585) 1437-1438.
[48] Armendares et al. (1971) Chromosome abnormalities in severe protein calorie malnutrition. Nature 232: 271-273.
[49] Mutchinick et al. (1979) Frequency of sister chromatid exchanges in severe protein calorie malnutrition. Annales du Genetique 22(3): 129-132.

Tinsley et al. (1970) (5.58 megarad = 55.8 kGy); Johnson-Arthur et al. (1971) (≥ 0.5 megarad = ≥ 5 kGy); and Renner (1977) (4.5 megarad = 45 kGy). Anderson et al. (1981) observed adverse effects following irradiation of only one of five irradiated rodent diets and the doses were extremely high compared to phytosanitary irradiation at 1 or more megarad (10 or more kGy). FSANZ also notes that numerous irradiated rodent diets are commercially available and rodent models of severe immunodeficiency have been maintained on them for many generations.

- Studies using microbes or insects, which include those of Swaminathan et al. (1963); Rinehart and Ratty (1965, 1967); and Kesavan and Swaminathan (1969, 1971) as test systems are not relevant to human risk assessment. Some references, including Shaw and Hayes (1966) and Kesavan and Swaminathan (1966) are to *in vitro* studies which have not been reproduced in living human or animal models.
- Two older articles, that of Lofroth (1966) and Schubert (1969) called for testing that has since been done. Lofroth based his concerns on experiments in which he used doses of irradiation much higher than those used for phytosanitary irradiation. Schubert cited evidence that has since been shown to be not reproducible, recommended mutagenicity assays that have since been discredited, and expressed concerns around substances that have since been shown to be not of concern.
- The paper by Tritsch (2000) is an opinion piece which is not supported by findings of hazard assessments by FSANZ and other regulatory authorities. His assertion that all cancers have a latent period of 'four to six decades' is incorrect. Tritsch's prediction of increased cancer has been shown to be groundless. The age-adjusted rates of almost all types of cancer have either remained the same over the last 50 years, or decreased.
- Only one cited reference could not be reviewed by FSANZ. A copy of the FDA report written by Spiher (1968) could not be located. However FSANZ notes that the current position of the US FDA is supportive of food irradiation, see https://www.fda.gov/food/irradiation-food-packaging/overview-irradiation-food-and-packaging.

(c) References to studies that submitter (Organic Industries of Australia) suggested should be included in FSANZ's safety assessment

- Reproductive problems, cancer in mammals *Food irradiation: An FDA report. FDA Papers, Oct. 1968.*
  The 1968 FDA report could not be accessed. However the current position of the US FDA is supportive of food irradiation, see https://www.fda.gov/food/irradiation-food-packaging/overview-irradiation-food-and-packaging.
- Fatal Internal Bleeding in Rats (I) *Vitamin K deficiency in rats induced by feeding of irradiated beef. Journal of Nutrition, 69:18-21, 1959. (Cosponsored by the Surgeon General of the US Army).*
  This article, by Metta et al. (1959), identifies the cause of haemorrhagic disease in rats as vitamin K deficiency, not any radiolytic product.
- Fatal Internal Bleeding in Rats (II) *Influence of age, sex, strain of rat and fat soluble vitamins on hemorrhagic syndromes in rats fed irradiated beef. Federation Proceedings, 19:1045-1048, 1960. (Cosponsored by the Surgeon General of the US Army).*
  This study is by Mellette and Leone (1960). It clearly identifies the cause of haemorrhagic disease in rats as vitamin K deficiency and the authors note that non-irradiated diets may cause the same disease due to the same deficiency.
- Fetal Deaths in Mice *Irradiated laboratory animal diets: Dominant lethal studies in the mouse. Mutation Research, 80:333-345, 1981.*
  Anderson et al. (1981). Fetal deaths were observed following irradiation of only one of five irradiated rodent diets and the doses were extremely high compared to phytosanitary irradiation at 1 or more megarad (10 or more kGy). The findings are therefore not relevant.
- Embryo Deaths in Mice *Pre-implantation death of mouse eggs caused by irradiated food. International Journal of Radiation Biology, 18:201-216, 1970.*
  Moutschen-Dahmen et al. (1970). (Alleged pre-implantation loss in mice). The radiation dose was 5 megarads, equal to 50 kGy and therefore much higher than the dose used for phytosanitary irradiation.
- Radioactive Organs and Excrement in Rats *Biochemical effects of irradiated sucrose solutions in the rat. Radiation Research, 37:202-215, 1969.*
  De et al. (1969). The results of the study are misrepresented. As part of this study, the rats were intentionally fed sucrose labelled with a radioactive tracer (carbon-14) and the study authors make it very clear that the detected radioactivity in organs and faeces came from that tracer. Irradiated food is not radioactive. FSANZ notes that De et al. state 'Assessed by various parameters, no deleterious effects could be observed in rats fed the irradiated sucrose solution for a period of 8 weeks.'
- A Thalidomide Warning (I) *Mutagenicity and cytotoxicity of irradiated foods and food components. Bulletin of the World Health Organization, 41:873-904, 1969. (Cosponsored by the US Atomic Energy Commission and Food and Drug Administration)* and A Thalidomide Warning (II) *Mutagenicity and cytotoxicity of irradiated foods and food components.* Bulletin *of the World Health Organization, 41:873-904, 1969. (Cosponsored by the US Atomic Energy Commission and Food and Drug Administration).*
  Two bulletins of the WHO. These opinions are outdated and have been overturned. WHO now supports phytosanitary irradiation. Comparison to thalidomide is not a valid analogy. The mechanism by which thalidomide causes phocomelia is well understood and has no parallel in consumption of irradiated produce.
- A Host of Problems *Cytotoxic and mutagenic effects of irradiated substrates and food material. Radiation Botany, 11:253-281, 1971.*
  Kevasan and Swaminathan (1971). This study is not relevant because the test organisms used were microorganisms and insects. FSANZ does not recognize microorganisms or insects as models for human toxicity; only mammalian models. Causing adverse effects in insect pests is one of the purposes of phytosanitary irradiation.
- A Cancer Warning *Food Irradiation. Nutrition, 16:698-701, 2000.*
  Tritsch (2000). This is one person's opinion, not a scientific study. The assertion that all cancers have a latent period of 'four to six decades' is incorrect. Tritsch's prediction in 2000 of increased

cancer has not come to pass. The age-adjusted rates of almost all types of cancer have either remained the same over the last 50 years, or actually decreased. Hazard assessments by FSANZ and other regulatory authorities do not support the opinion of Tritsch.

- Mutations in Fruit Flies *Mutations: Incidence in Drosophila melanogaster reared on irradiated medium. Science, 141:637-638, 1963.*
  Swaminathan et al. (1963). This study is not relevant to hazard assessment of irradiated fruit and vegetables to humans or other mammals. Causing adverse effects in insect pests, including fruit flies, is one of the purposes of phytosanitary irradiation.

- Fatal Vitamin E Deficiency in Rats *Growth, reproduction, survival and histopathology of rats fed beef irradiated with electrons. Food Research, 20:193-214, 1955.*
  Poling et al. (1955). This study is not relevant to the current application, which concerns fruit and vegetables because the diet of the rats was beef. The adverse effects were clearly linked to vitamin E deficiency. The effects of phytosanitary irradiation on dietary intake of vitamins is considered by FSANZ.

- Chromosomal Damage to Human Cells (I) *Effects of irradiated sucrose on the chromosomes of human lymphocytes in vitro. Nature, 211:1254-1255, 1966* and Chromosomal Damage to Human Cells (II) *Cytotoxic and radiomimetic activity of irradiated culture medium on human leukocytes. Current Science, 16:403-404, 1966.*
  These are two papers on chromosomal damage on lymphocytes and leukocytes *in vitro, by* Kevasan and Swaminathan (1966a, b). The *in vitro* findings from these studies have been shown in subsequent research to not occur in living mammals consuming irradiated food.

- Toxic Chemical Formed in Food Containing Fat *Genotoxic properties of 2-dodecylcyclobutanone, a compound formed on irradiation of food containing fat. Radiation Physics and Chemistry, 52:39-42, 1998. (Cosponsored by the International Consultative Group on Food Irradiation).*
  Delincee et al. 1998 (alleged genotoxicity of 2-DCB). See the summary of the paper by Song et al. (2018) in the Hazard Assessment (Section 3.2.1 of SD1). There was no evidence of genotoxicity of 2-DCB in the assays conducted by Song et al. (2018). The weight of evidence is that 2-ACBs are not genotoxic.

(d) References to studies provided by submitters that relate to safety of irradiated food and formation of radiolytic compounds, free radicals, carcinogens, and other toxic chemicals

- **Issue:** Submitter commented that small studies have been done in China and India on animals where studies show vitamin deficiencies, increased tumours, reproductive failures and kidney damage in both humans and animals; and lack of long term trials on the human consumption of an irradiated diet have been conducted. The longest, a Chinese study, was 15 weeks in duration.

  FSANZ response: No links or details of the alleged studies in China or India were provided. FSANZ was not able to locate the studies to verify the submitter claims.

- **Issue:** Submitter cites research by Bhaskaram and Sadasivan (1975) showing irradiated wheat caused abnormal mitosis and cellular production leading to polyploidy (doubling of the chromosomes) in cells leading to genetic disorders and tumor growth.

  FSANZ response: The study by Bhaskaram and Sadasivan (1975) alleging chromosomal abnormalities in malnourished children who consumed irradiated wheat lacked statistical power, and attempts to replicate the results in experimental animals (George et al. 1976)[50] and in humans have not been successful (Truswell 1987)[51]. Malnutrition has been shown to cause a significant increase in the frequency of chromosomal abnormalities in children (Armendares et al. 1971[52]; Mutchinick et al. 1979[53]). It is therefore unlikely that the chromosomal defects in the children were due to the wheat, and most likely that they reflected malnutrition.

- **Issue:** Submitter cites report (Bradford et al. 2004) that examined both sides of the irradiation debate and found that current evidence does not exist to substantiate the support or unconditional endorsement of irradiation of food for consumption[54].

  FSANZ response: Bradford et al. (2004) came to conclusions contrary to those of FSANZ, the WHO, EFSA, the US FDA, Health Canada and other regulatory authorities. It should be noted that the cited article refers to irradiation for the purpose of killing bacteria, not phytosanitary irradiation to control insect pests. This application concerns phytosanitary irradiation which uses a lower dose of radiation.

- **Issue:** Submitter refers to 'an important 2001 study' that linked 2-ACBs in irradiated foods to colon tumor promotion in lab rats, and to genetic, DNA, and cellular damage in rats. Submitter considers that as no vigorous scientific evidence has ruled out this possibility of exposure to harmful compounds, all irradiated foods should be excluded from the human food supply immediately.

  FSANZ response: The 'important 2001 study' appears to be that of Raul et al. (2002). This study was reviewed by FSANZ in the Hazard Assessment of A1038 and was therefore not revisited as part of the current assessment. The study was flawed due to small group sizes, relatively short exposure duration and absence of additional negative controls to allow an assessment of the background incidence of pre-neoplastic and neoplastic lesions (i.e. without 2-tDCB/2-tDeCB and azoxymethane treatment; 2-tDCB/2-tDeCB without azoxymethane treatment). There have been a large number of long-term studies in rats conducted on irradiated food that show no evidence of carcinogenicity, and therefore the Raul et al. (2002) study is not considered to be supported by other evidence. It should be noted that exclusion of 'all irradiated foods' from the human food supply would exclude plants and plant products from the human food supply, because plants are

[50] George et al. (1976) Frequency of polyploidy cells in the bone marrow of rats fed irradiated wheat. Food and Cosmetics Toxicology 14: 289-291.
[51] Truswell (1987) Food Irradiation British Medical Journal 294(6585) 1437-1438.
[52] Armendares et al. (1971) Chromosome abnormalities in severe protein calorie malnutrition. Nature 232: 271-273.
[53] Mutchinick et al. (1979) Frequency of sister chromatid exchanges in severe protein calorie malnutrition. Annales du Genetique 22(3): 129-132.
[54] Bradford et al. (2004) Health concerns regarding consumption of irradiated food. International Journal of Hygiene and Environmental Health 207(6): 493-504.

grown in sunlight, a source of ionizing radiation.

- **Issue:** Submitter cites radiation changes the composition of the food producing 'radiolytic products' including free radicals, various hydrocarbons, formaldehyde, amines, furan and 2-alkylcyclobutanones (2-ACBs) (FSANZ A1092). 'Some of these may be harmful. Furan is carcinogenic to rats and mice, and is classified by IARC as possibly carcinogenic to human beings (Seok et al. 2013). FSANZ does not deny that radiolytic products may be harmful; FSANZ states that 'Radiolytic compounds generated through food irradiation are not produced at levels that are likely to result in harm.' But the levels can change. There is no guarantee that FSANZ will not approve an increase in the permitted radiation exposure levels. Already, some foods, herbs, spices and plants for herbal infusions are approved at much higher levels'.

  FSANZ response: The submitter is referred to the discussion of furan and other radiolytic products in Section 3.2.1 of the Hazard Assessment for Application A1193. Furan is specifically addressed in Subsection 3.2.2.1. Irradiated fruit and vegetables are not a significant source of furan in the diet, when compared to other dietary sources of furan.

- **Issue:** Submitter comments that according to the Food Commission, Britain's leading independent watchdog on food issues, irradiation disrupts the molecular structure of food, producing free radicals (which then react to form by-products not otherwise found in nature), which are part of the pathogenesis of multiple illnesses – asthma, IBD, autoimmune diseases, hepatitis, ulcerative colitis and some cancers. Research also shows that irradiation forms volatile toxic chemicals such as benzene and toluene, chemicals known, or suspected, to cause cancer and birth defects. It also produces another potentially harmful, toxic chemical formaldehyde. Irradiation has also been shown to cause the low-level production of furans (similar to cancer-causing dioxins) in fruit juice. See Effect of ionizing radiation on furan formation in fresh-cut fruits and vegetables - https://tinyurl.com/y5e6cqru.

  FSANZ response: The various radiolytic products including free radicals, benzene, toluene, formaldehyde and furans have been discussed in successive hazard assessments in response to applications for phytosanitary irradiation considered by FSANZ and listed in Table 1 of SD1. As FSANZ has repeatedly noted, the levels of free radicals, benzene, toluene and furans generated by phytosanitary irradiation are negligible when compared to the levels found in the diet generally, either because the substances are naturally found in some foods or are generated by such processes as cooking. Furan is specifically discussed in the Hazard Assessment for the current application and the much more significant sources of furan are described. FSANZ further notes that free radicals are highly unstable and reactive, with very short half-lives, and would not still be present in irradiated produce at the time of sale. The submitter has not presented any evidence that free radicals are causative agents of asthma, IBD, autoimmune diseases, hepatitis, ulcerative colitis or cancer.

- **Issue:** Submitter raises the concern that the maximum level of radiation permitted may be increased in the future. An increase will bring greater loss of nutritional value and an increase in radiolytic products. This was found by Calucci et al. (2003) who looked at the impact of 10 kGy irradiation on the content of free radicals and some nutrients in spices and herbs. Irradiation resulted in an increase in free radical content and significant loses in vitamin C and carotenoids.

  FSANZ response: Any increase in radiation dose will require a further application to FSANZ, at which time the loss of nutritional value and increases in radiolytic products would be the subjects of nutritional and hazard assessments respectively. At this time the work of Calucci et al. (2003) is not relevant because a radiation dose exceeding 1 kGy is not permitted.

- **Issue:** Submitter comments that uncontested basic science shows that ionising radiation powerfully oxidises a wide range of substances in foodstuffs and results in a cascade of oxidation effects resulting from formation of nitric oxide, including direct formation of the persistent radical oxidant nitrogen dioxide (known to trigger lipid auto-oxidation, leading to cell-membrane damage) and of peroxynitrite (leading to inflammatory stress and carcinogenesis). The damage that these and other oxidation reactions cause in microbes and in plant gametes mirrors the damage they cause in the humans who consume the reaction by-products, which include several highly reactive oxygen species and the oxidants that they form.

FSANZ response: There is no evidence that oxidising substances formed as radiolytic products cause any damage in human beings or other mammals. Household cooking also involves oxidation of foodstuffs and radiolytic products, with the exception of 2-ACBs, are also formed during cooking or other thermal treatments. Phytosanitary irradiation has a long history of safe use in human beings and in multigenerational and chronic studies in animals, and there is no evidence that consumption of irradiated fruits or vegetables results in inflammatory stress or carcinogenesis. Nitrogen dioxide and peroxynitrite are highly reactive, and therefore have extremely short half-lives in biological systems including plant material. Thus, nitrogen dioxide and peroxynitrite formed during phytosanitary irradiation would not be present in produce at the time of sale.

- **Issue:** Submitters comment that FSANZ has previously relied on one 2008 study, by Variyar et al. which indicated that 2-ACBs were found in non-irradiated cashews and nutmeg. The findings have never been duplicated. In 2011 EFSA stated: 'As no further evidence of the natural occurrence of 2-ACBs has yet been reported, it would be pertinent to treat these findings with some caution until the results are validated by further experimental work.'[55] However FSANZ continues to include Variyar et al. in its list of references. Whether or not these chemicals are unique to irradiation or naturally formed, they have been linked to cellular damage.

  FSANZ response: FSANZ discussed the paper by Variyar et al. (2008) and the inability of other research teams to replicate those findings in subsection 3.2.1.1 of the Hazard Assessment in SD1. It is appropriate to provide a full reference to a published paper even if it is concluded, in the main body of the document, that the findings in the paper may be incorrect.

- **Issue:** Submitter comments that when irradiated, food rich in sugars produce many organic peroxides and amino acid-peroxide adducts. Several of these are known to be carcinogenic and possibly mutagenic.[56] Animals fed irradiated foods in experiments dating back 50 years have suffered premature death, mutations and other genetic abnormalities, fetal death and other reproductive problems, immune system disorders, fatal internal bleeding, organ damage, tumors, stunted growth and nutritional deficiencies.[57]

  FSANZ response: The radiolytic products have been subject to risk assessment by FSANZ; see the Hazard Assessment in SD1. The cited paper by Kevasan and Swaminathan (1971) is not relevant because the test organisms were microorganisms and insects. FSANZ does not recognize microorganisms or insects as models for human toxicity; only mammalian models.

[55] European Food Safety Authority (EFSA), Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) (2011). Scientific Opinion on the Chemical Safety of Food. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.1930.

[56] https://www.sciencedirect.com/science/article/pii/S0033756071900172?casa_token=uLMkdrjfjswAAAAA:zixb1Z5MKba3F6G3oO6cqGK502D-NQH6whdU1ffSQZKGg58jOB_7PHp_dKb4aMWSSA0r9gcS (1971).

[57] https://www.citizen.org/wp-content/uploads/badtaste.pdf (2002).