Submission to FSANZ
Comments on Application A1193:
Irradiation as a phytosanitary measure
for all fresh fruits and vegetables

Food Irradiation Watch

[redacted]

www.foodirradiationwatch.org

GeneEthics

[redacted]

with

Friends of the Earth
GM-Free Australia Alliance
Australian Food Sovereignty Alliance

"*Fruits and vegetables are the cornerstone of a healthy and varied diet. They provide the human body an abundance of nutrients, strengthen immune systems and help lower risks for a number of diseases. By declaring 2021 as the International Year of Fruits and Vegetables, we are taking a closer look at a critical sector and urging the adoption of a more holistic approach to production and consumption that benefits human and environmental health."*

UN Secretary-General, António Guterres, 15/12/2020[1]

But meanwhile, FSANZ is set to approve irradiation of ALL fresh fruits and vegetables, degrading the nutritional value, safety, and integrity of foods in our daily diet that best promote health, wellbeing and prevent disease.

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[1] Guterres, A. UN Secretary-General declares 2021 the International Year of Fruits and Vegetables. https://www.un.org/sg/en/content/sg/statement/2020-12-15/secretary-generals-message-launch-of-the-international-year-of-fruits-and-vegetables-2021-scroll-down-for-french-version

Executive Summary

Application A1193: Irradiation as a phytosanitary measure for all fresh fruits and vegetables proposes a significant departure from case by case irradiation approvals. It should have been classified as a major change to food regulations in Australia and New Zealand and processed as such, with two rounds of public consultation.

We oppose A1193 for the following reasons:

- The wholesomeness, nutritional values and quality of food is impacted by irradiation.
- The environmental and social costs of irradiating our fresh food are unacceptable.
- We question the capacity of the regulatory system to monitor and enforce safety and dietary integrity throughout a process for which it and the Food Forum have not developed specific and detailed guidelines, giving the nuclear and horticulture industries a free hand.
- The applicant and FSANZ have failed to prove that there is a technical need for the irradiation of ALL fresh fruits and vegetables, as many other fruit fly management options are available.
- No regulatory provisions exist to ensure that irradiation cannot be illegally used to sterilize fresh produce that has microbial or plant pathogen infestations, or to extend its shelf life, which are collateral but unapproved uses.
- FSANZ's SD1 Supporting Document displays bias, advocates for the application, and ignores substantial counter-evidence.
- A1193 would allow any fresh fruit or vegetable to be irradiated without any individual pre-market clearance or impact assessment.
- The proposed labeling of irradiated fruits and vegetables is deceptive and misleading.

Recommendations

We therefore recommend that FSANZ reject proposal A1193. In brief, the grounds for our recommendation are:

- The safety and nutritional integrity of irradiated foods is not established;
- The application and the assessment are flawed in the ways we discussed;
- The technological need for irradiation has not been established;
- FSANZ and the industry fail to demonstrate the duty of care to manage an irradiation industry that serves the public's best interest;
- A1193 offers no credible benefits to Australians or New Zealanders and may, in fact be detrimental to health, horticultural industries and the economy;
- If A1193 were approved, the Australian and New Zealand public would be unfairly and unnecessarily exposed to further risks, costs and hazards;
- Labelling of irradiated food is inadequate to ensure informed choice;
- The regulator has failed to adequately engage the public;
- The exclusion of dried pulses, legumes, nuts and seeds from A1193 shows there are good grounds for not irradiating some fruits and vegetables, so we oppose any blanket approval.

FSANZ must:

- Cancel all previous irradiation approvals and/or place a moratorium on the irradiation of all foods in Australia and New Zealand, and the importation of irradiated food products, until

independent and competent experts have fully explored the aetiology of the toxic effects and fatalities observed in cats that resulted from eating irradiated animal feed.

- Overhaul FSANZ's assessment processes, in particular its communications and public engagement processes, to ensure that they are non-biased, transparent, easy to understand and actively facilitate public involvement in regulatory processes.

If FSANZ continues to support irradiation and/or approve A1193, FSANZ must:

- Put in place protocols to ensure that if a product is irradiated, it is irradiated only for the permitted purpose, at the minimum dose prescribed for its intended purpose, and that this is recorded and monitored.
- Work with industry, states and territories to provide a framework to monitor radiation doses, irradiation purposes, distribution of irradiated foods, irradiation packaging and to enforce safety guidelines in the public interest.
- Conduct research that focuses on the impacts not of sales but of consumption of irradiated foods on community health, environmental health, agriculture, trade and well-being
- Place the onus for addressing safety concerns and impacts on the applicant government, and the nuclear and horticultural industries, which promote and utilize food irradiation.
- Overhaul labelling regulations to ensure consistent, clear, concise, non-biased and easy-to-understand labelling of all irradiated products.

Irradiated v Fresh: danger of misrepresentation

Marketing any irradiated food as "fresh" and labelling it as such raises very significant issues of false and misleading representations.

The irradiation of fruits and vegetables typically involves their exposure to the energy equivalent of between 1.5 million and 10 million x-rays. Used as a fruit fly larvae treatment, food irradiation also extends shelf life, sanitises, and alters the nutritional value of the treated foods. The substantial and significant changes that irradiation makes to fruits and vegetables cannot be discerned with our senses - **Sight, Sound, Smell, Taste, and Touch.**

According to the Cambridge Dictionary, fresh means:

> "(of food or flowers) in a natural condition rather than artificially preserved by a process such as freezing…"[2]

Just as shoppers expect to be told if fish, meat or other produce has been frozen, then thawed for sale, irradiated fruit and vegetables are no longer fresh and should not be described or marketed as such.

There are ample examples of governing bodies referring to Food Irradiation and irradiated foods as 'Processed', both locally and overseas. In recognition that irradiation alters the nature of food, irradiation is regulated as a food additive in the US and irradiated food is labelled accordingly. The 1958 Food Additives Amendment describes irradiated food as "adulterated." [3]

[2] https://dictionary.cambridge.org/dictionary/english/fresh
[3] http://www.fda.gov/Food/IngredientsPackagingLabeling/IrradiatedFoodPackaging/default.htm

Both the applicant, the Queensland government, and Victorian governments refer to irradiation as processing. [4]

The Victorian government refers to irradiation as "a form of food processing that can extend shelf life and reduce spoilage." [5]

According to the *Australian Competition and Consumer Commission* (ACCC), "'Fresh' generally refers to food that is put on sale at the earliest possible time and close to the state it would be in at the time of 'picking', 'catching', producing etc. The term "fresh" generally implies that food has not been frozen or preserved." The ACCC Food Descriptor guidelines also make it clear that "silence" or "omission" of information is also potentially misleading.[6]

It is clear that, while it may appear to be so, irradiated food is not fresh – it is intentionally and significantly altered. Even with labelling, irradiated foods are likely to be referred to and marketed as fresh.

FSANZ has a clear responsibility to require state and local food authorities, food industry supply chains and retailers, to ensure that irradiated produce is honestly marketed without deceiving shoppers that it is fresh.

Overview of irradiation impacts

On October 30, 2020, Food Standards Australia New Zealand (FSANZ) announced a six-week public consultation for A1193, the Queensland government's application for approval to irradiate all fresh fruits and vegetables.

Herbs, spices, herbal infusions and nine tropical fruits, persimmons, tomatoes and capsicums had been approved for irradiation in Australia and New Zealand. Pet foods, medicinal goods, and seeds and grains for animal consumption may also be irradiated. These are not classified as "food" under Australian law as they fall under different regulations and – other than cat and dog food - require no labelling.

Numerous studies have shown the potential health risks and hazards that irradiated foods pose. The approval of ALL fruit and vegetables includes all those foods regularly eaten by large sections of society, that could significantly increase the amount of irradiated food in the community's diet. These biases could adversely affect the nutritional value and safety of significant core components of the Australian and New Zealand food supplies. Those groups of people who make highly selective food choices for cultural, religious, dietary or life-style reasons may be especially affected, but little research has been done on these potential impacts.

While FSANZ acknowledges in its assessments and fact sheets, that irradiation may deplete the vitamin and nutritional content and value of food, it still justifies irradiation with claims that the approved foods will make up a minimal part of the Australian and New Zealand diets.

But that will dramatically change if all fruits and vegetables, which governments and health promotion organisations advocate as essential for good health, are irradiated. These foods make up a large core component of the regular diet of all Australians and New Zealanders.

[4] https://www.health.qld.gov.au/__data/assets/pdf_file/0028/721486/food-irradiation.pdf
[5] https://www.betterhealth.vic.gov.au/health/HealthyLiving/food-irradiation
[6] 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

There is scant data to support claims that irradiation has been proven safe as there have been no long-term studies of the human consumption of irradiated foods. While the purchase of irradiated food products is being monitored for marketing purposes, there is scant evidence of any monitoring of the personal or public health impacts of their consumption. Indeed, "consumption data are not available."

> *"The USA is the second greatest user of food irradiation by volume after China. No consumption data are 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 be presumed that retailers are actually selling most of the product."* [7]

Safety and efficacy cannot be "presumed," with "no consumption data available". There is no basis for a reliable or honest scientific statement on long term safe human consumption of irradiated foods.

Lack of scientific rigour

Australians and New Zealanders expect our food regulator to be the public's scrupulous, stringent and non-biased referee in its assessment of new foods under Standard 1.5. FSANZ, the Food Forum and the Standing Committee are also expected to adhere to internationally recognised standards of peer-review for the science it relies upon when making decisions and to present relevant science with honesty and integrity**.** The approach to scientific substantiation in FSANZ's assessments of irradiation have been unsatisfactory, especially its over-generalisations based on minimal evidence. As a result, the potential impacts of this expansion of irradiated foods on nutrition and public health are misrepresented.

As therapeutic goods, animal feed and agricultural products may also be irradiated, FSANZ is not the only regulatory body involved in irradiation approvals and monitoring. Federal government information from the Therapeutic Goods Administration and Biosecurity Australia acknowledge and address problems with irradiation as a production practice for the non-food products that the public consumes.

The Therapeutic Goods Administration permits irradiation as a decontamination treatment and requires monitoring of its potential adverse impacts.

> *"Substances may be sterilised using ionising radiation. You should consider what radiolytic products may be formed in the substance and what constituents of the substance may be affected by such treatment, for example: vitamin A. You should have documentation about substances that have been irradiated, monitor levels of radiolytic products or constituents and, if necessary, establish and document limits."*[8]

Biosecurity Australia permits irradiation for quarantine purposes yet also notes:

> ***"****It is now well established 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."*

> *"The available scientific evidence supports the use of irradiation as a biosecurity treatment for pet food only in exceptional circumstances. It is not supported for those products likely to be consumed as a significant proportion of an animal's diet (e.g. kibble)."* [9]

[7] FSANZ A1092, SD1, p3
[8] 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
[9] https://www.agriculture.gov.au/biosecurity/risk-analysis/animal/gamma-irradiation/questions-and-answers

Rather than looking for ways to communicate the "safety and benefits" of irradiation, FSANZ should demonstrate the same candour when representing the public nutrition, health and safety issues around irradiation of food.

Our concerns with FSANZ's approach to its communications about irradiation are exemplified, but are not limited to, the following:

FSANZ makes indefensible claims such as that "there would be **no impact** on dietary intakes from consuming irradiated produce" [10] despite clear evidence and FSANZ's own findings.

Evidence which contradicts this assertion is FSANZ's own findings regarding the impacts on vitamins, including vitamin C:

> *"Irradiation of leafy vegetables, Brassicas, and roots and tubers at doses of up to 1 kGy caused only small losses of 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 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."*[11]

FSANZ contradicts itself by acknowledging irradiation impacts on diet and then downplaying them. It's lack of scientific rigour is demonstrated by its vague estimations that impacts are "likely to be low':

> "*FSANZ considers that based on the available evidence the effect of irradiation on the micronutrient content of fruit and vegetables* ***is likely to be low****. The range of fruit that has been assessed is comprehensive, accounting for most types of fruit consumed in Australia and New Zealand; however, the range of vegetables examined is not as comprehensive. While the body of evidence for vegetables suggests that irradiation-induced losses of micronutrients that are sensitive to irradiation is also small, there are examples of a few foods – spinach and rocket – in which losses are higher."*[12]

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:

> "However, there will only be a relatively small proportion of both imported and domestically produced fruit and vegetables in Australia and New Zealand treated by irradiation, with some commodities not requiring irradiation due to localised consumption and technological reasons. ***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 impact on population nutrient intakes from consuming irradiated produce."*** [13]

FSANZ also makes incorrect assertions about Vitamin A (retinol) (specifically mentioned in the TGA directive) which is highly sensitive to irradiation" excluding it from the assessment. Information about

[10] A1193, SD1, p 58
[11] A1193, SD1, pii
[12] ibid
[13] A1193, SD1, p ii

> "***Vitamin A (retinol) which is highly sensitive to irradiation was excluded from the nutritional assessment because retinol is not present in plant foods."*** [14]

This is incorrect as:

> **"Retinol** is an active form of **vitamin A**. It is found in animal liver, whole milk, and some fortified **foods**. Carotenoids: Carotenoids are dark-coloured dyes (pigments). They are found in **plant foods** that can turn into active form of **vitamin A**."[15] [16]

FSANZ fails to address key nutritional issues due to an acknowledged lack of scientific evidence regarding highly sensitive compounds:

> "***Thiamin and vitamin E, also highly sensitive to irradiation, were considered but a firm judgement about the extent of irradiation-induced losses is not made because too few relevant studies were identified."*** [17]

FSANZ takes an odious comparison approach when it acknowledges but downplays the significance of the nutrient loss that irradiation causes, by comparing it to other food processes. Genuinely fresh fruits and vegetables should be delivered without delay, with minimal other processing and no cooking.

> *"FSANZ has also assessed the changes that can occur in nutrient content as a result of postharvest storage, processing and cooking, to compare with post-irradiation changes…* ***The losses noted as a result of storage, processing and cooking were often greater than losses determined as a result of irradiation."*** [18]

This claim is a red herring as, for example, most shoppers do not cook mangoes. Irradiation deceitfully undermines their legitimate assumption that the "fresh" fruit they purchase has not already been processed in a way that substantially diminishes its nutrient content. Irradiation is an invisible process, with impacts unseen and unexplained. A shopper may fully expect some cool storage in food transportation and retail but they do not expect fresh fruits and vegetables to have incurred additional nutrient loss due to being "pre-cooked" with irradiation.

FSANZ's regulatory bias shows up in its omission of Australian-centred research into irradiation's link to neurological disorders in cats. In dismissing feline neurological disorders and fatalities as species specific, it relies on unsubstantiated science, fails to source or require additional research, bases its assessments on assumptions and conjecture, and makes promotional statements rather than candidly and honestly stating the known scientific facts and their short-comings.

Australian in vivo experience of detrimental impacts of irradiation: Between 2008 and 2009, approximately 100 Australian cats developed neurological disorders which led to their paralysis and, in some cases, death. The cause was identified as the consumption of irradiated cat food imported from Canada. As a result, irradiated cat food is now banned in Australia. Irradiated dog food also carries a warning not to feed it to cats.

In past reviews, FSANZ acknowledged the feline pathogenic model of toxigenicity related to the consumption of irradiated pet food but provided no data or insights into the exact mechanisms involved in this toxic effect. To arrive at FSANZ's conclusion that these effects are cat-specific, a diversity of other

[14] A1193, SD1, pii
[15] MedlinePlus. https://medlineplus.gov/ency/article/002400.htm
[16] Gilbert C, Community Eye Health. 2013; 26(84): 65. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3936685/
[17] A1193, SD1, pii
[18] A1193, SD1, p 54

animal models would have to have been tested. Yet FSANZ still fails to present data to substantiate its conclusion that toxic irradiated animal feed only adversely affects cats, not other animals or humans.

Until the specific mechanisms of toxicity are elucidated, it is irresponsible to declare the disease and deaths among cats "not relevant" to humans. A pertinent analogy is that thalidomide is not teratogenic in rodents, but is devastating for humans *in utero.* The European Food Safety Authority has stated the relevance of the cat disease to human health impacts as a result of food irradiation still needs clarification.[19]

Furthermore, the cat case shows that FSANZ is guilty of a failure of regulatory duty of care to the public in light of unfavourable research on the health impacts of irradiation. Research indicating the potential for adverse neurological impacts on cats had been conducted prior to the irradiation of Canadian cat food for the Australian market. But, despite the identified risks, regulators allowed cat food irradiation as a quarantine measure.[20][21]

We note that pet food irradiation does not fall under FSANZ's jurisdiction and the cat food in question was irradiated at higher levels because it contained animal ingredients. Arguments that the high dose at which the cat food was irradiated do not negate the observed impacts or the potential for collateral impacts from such treatments at any dose. Other pet food, animal feed and other products which are not regulated as food may still be irradiated at up to 50kGy, higher than permitted for food in Australia and New Zealand. But herbs, spices and herbal infusions are already treated at up to 30kGy. While the current Standard prescribes up to 1kGy for fruit, FSANZ aims to align with Codex standards which already permit a maximum generic dose of "up to 10kGy, except when necessary to achieve a legitimate technological purpose." [22] There is no guarantee that higher doses will not be permitted in Australia in the future.

Radiolytic products are significant

Contrary to FSANZ's assertions, irradiated food is not "chemical free" as irradiation can cause the accumulation of radiolytic compounds, such as alkylcyclobutanones, to levels not observed in un-irradiated foods. For instance, the chemical changes to meat in response to irradiation are detectable, repeatable and specific. There are at least five radiolytic biomarkers available 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 other 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.

To downplay the significance of radiolytic products, FSANZ had made assertions based on un-duplicated research presented by the nuclear industry. In Application A1069: Irradiation of tomatoes and capsicums, as the first dot point in the cover page summary, FSANZ claimed: "Compounds potentially formed during food irradiation, such as 2-alkylcyclobutanones (2-ACBs), are found naturally in non-irradiated food." [23]

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[19] European Food Safety Authority, EFSA Journal 2011:9(4):1930 Scientific Opinion on the Chemical Safety of Irradiation of Food, p1

[20] https://www.avma.org/javma-news/2009-08-15/australia-halts-irradiation-imported-cat-food-after-link-neurologic-damage

[21] European Food Safety Authority, EFSA Journal 2011:9(4):1930 Scientific Opinion on the Chemical Safety of Irradiation of Food, p31

[22] General standard for irradiated foods CODEX STAN 106-1983, rev.1-2003

[23] FSANZ Application A1069 Irradiation of Tomatoes & Capsicums Supporting Document 2 Risk and technical assessment report, pi

To make this assertion, FSANZ relied on one 2008 study, by Variyar et al which indicated that 2-ACBs were found in non-irradiated cashews and nutmeg. [24] The findings have never been duplicated. After conducting an extensive irradiation literature review, in 2011 the European Food Safety Authority states: "As no further evidence of the natural occurrence of 2-alkylcyclobutanones (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." [25]

FSANZ continues to include Variyar et al. (2008) in its list of reference materials.[26]

Whether or not these chemicals are unique to irradiation or naturally formed, they have been linked to cellular damage. Many naturally occurring substances, such as uranium, asbestos or even carbon dioxide, can be harmful.

Claims that fruits and vegetables are not significantly changed due to irradiation processing are also misleading. For instance, delayed ripening – an acknowledged and sometimes sought-after outcome of irradiation - indicates major, biologically significant compositional changes in the produce. For unscrupulous food marketers seeking a competitive advantage, delayed ripening and extended shelf life may be desirable collateral outcomes from a phytosanitary treatment.

Dismissal of impacts despite lack of detailed dietary modelling

We challenge the FSANZ assertion, first made in 2014, that no further dietary assessment is needed or should be required for irradiated foods. In its report "Nutritional impact of phytosanitary irradiation of fruits and vegetables (February 2014), FSANZ let the public down by basing its assessments on evidence tainted with pro-irradiation bias, and un-peer-reviewed and unpublished research findings, that the applicants and their fellow-travellers had commissioned or conducted.

The report, upon which much of the A1193 application and SD1 are based, is primarily a literature review which draws heavily for validation on unpublished research that the Queensland Government earlier conducted. The literature search conducted in preparation of the 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 claim, occasionally made, that its reviews constitute peer-review. Over 150 different varieties of tropical fruits are grown in Tropical North Qld alone, yet few have ever been tested for the impacts of irradiation on their nutritional value or safety.

While claiming that its report "Nutritional impact of phytosanitary irradiation of fruits and vegetables (February 2014) covers most relevant impacts, FSANZ focuses its dietary intake assessment on vitamin C and β-carotene and asserts that a ***"detailed dietary intake assessment was not required for these."***[27]

FSANZ uses an array of questionable provisos to back its no-impact claims. Acknowledging depletions of key nutrients, they are repeatedly said to be insignificant, the amount of irradiated food produced and consumed is projected to be small, and/or the irradiated foods contribute little to the community's overall dietary intake. However, there is nothing to limit the expansion of

[24] FSANZ Application A1069 Irradiation of Tomatoes & Capsicums Supporting Document 2 Risk and technical assessment report, p6
[25] European Food Safety Authority (EFSA), Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF); Scientific Opinion on the Chemical Safety of Food Irradiation. EFSA Journal 2011;9(4):1930. p1
[26] A1193, SD1, p16
[27] A1193, SD1, p57

irradiation if ALL fruits and vegetables are approved. As Australians and New Zealanders increasingly adopt plant-based diets (12% now vegetarian[28]) these arguments for incaution are indefensible.

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 applicants appear to have squandered the opportunity to collect comprehensive and credible data from their commercial experience, resulting from FSANZ's previous approvals. Those applications were justified partly on the basis of the relatively low intake per capita of the approved foods.

However, application A1193 opens the floodgates and would facilitate 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. Irradiating fresh foods would also undermine, and may neutralise, the official promotions of fresh foods as essential to improving public health and preventing the onset of a variety of diseases. The Food Forum should at least consider and cost the extra imposts on the health system as a result of approving A1193. They should always be factored into FSANZ decisions.

Australia is leading the push for irradiation as a phytosanitary measure. Despite FSANZ's low estimates of the amount of irradiated foods that will be marketed, a blanket approval for all fresh fruits and vegetables would set the direction of increased irradiation, towards a more completely irradiated diet.

In 2003, concerns over the safety of irradiated food led the European Union to rule out further irradiation approvals. The Australian Senate followed suit with a call for approvals to be halted until further research has been conducted. Claims that irradiated foods are safe are indefensible as no research on long-term consumption of an irradiated diet have been conducted. The EU has maintained its position with no further general approvals.

Irradiation has been shown to deplete vitamin C, vitamin A, proteins, essential fatty acids and other nutrients in food and has been linked to health problems such as nutritional deficiencies, immune system disorders, abnormal lymph cells, and genetic damage. Increased approvals will see increased exposure to these risks. In this round of assessment, FSANZ found that spinach and rocket had greater than expected sensitivity to radiation, incurring significant nutrient loss.

A blanket approval will permit the irradiation of untested fruits and vegetables. The sensitivity and impacts are unknown. The cumulative impact thus cannot be ascertained. A significant impact on health thus cannot be ruled out.

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, with an indefinite quantity of untested irradiated fruits and vegetables able to enter the human food supply, without precise scrutiny, auditing or reporting, FSANZ reassurances are mere speculation. With little hard data from experiments or trials collected, the impacts remain unquantifiable and may be significant.

Failure to demonstrate capability to manage an expanding food irradiation industry

A blanket approval for all fruits and vegetables could see the amount of irradiated food significantly increase, with quality control left mainly to the discretion of the irradiation industry itself. Yet quality

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

assurance and independent monitoring systems are essential to prevent irradiation being misused to mask poor production practices, used inappropriately, or used in breach of approved standards.

Irradiation can be used to kill bacteria in food, but it does not remove the faeces, urine, pus and vomit that may often contaminate meat, or the pests, faeces, or other matter that may contaminate herbs, spices, or fruit and vegetables. Re-irradiation is also permitted under revised Standard 1.5.3 to treat post-irradiation contamination.

Application A1193 suggests that irradiation is necessary to kill fruit fly larvae, particularly of Queensland fruit fly, to enable increased interstate and international export trade of fruits and vegetables grown in areas that are potentially fruit fly infested. The proposal does not include a strategy that all jurisdictions would apply to ensure that irradiation is not used for prohibited purposes – to extend product shelf life; to remove pathogenic microbial contamination; or to sterilize fruits and vegetables.

FSANZ claims that produce marketed in the same quarantine region (for instance, Eastern Australia) won't be irradiated because it won't be necessary as the jurisdictions are already fruit fly infested. But it doesn't follow that the modest cost – 17 cents per kilogram - of irradiation treatment will necessarily limit its unnecessary or blanket use. Without a strict monitoring and enforcement regime, there are no guarantees that food won't be irradiated as a generic process, for distributor convenience or marketing advantage.

Without stringent controls in place, which require case by case evidence of the need for a phytosanitary treatment (insect pests in a product) and proof of a product's export destination (to a zone requiring phytosanitary control), a blanket approval of irradiation for all fruits and vegetables could see irradiation turned into a routine practice.

Even if all fruit and vegetables are permitted for irradiation, without one simple, reliable and affordable test for irradiated foods 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. The applicant has lodged no data to resolve these issues, yet the string of approvals including A1092 for many fruits and vegetables in 2016 has afforded the horticulture, nuclear and food retail industries ample opportunity to put monitoring and compliance systems in place and to conduct essential follow up research to validate earlier assumptions that impacts on diets, markets and the environment were acceptable.

A lack of independent pre-market clearance and assessment will lead to these industries both profiting from food irradiation and self-regulating use of the process. There is no assurance that the purpose and dosage of irradiation will be monitored – nor a framework for monitoring or quality control with independent case by case approval. This free for all is unacceptable.

Indeed, FSANZ already muddies the water around purpose, acting as a promoter of irradiation by referring to use of the treatment 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.

> *"Irradiation is a technique used to keep food safe. In Australia it is mostly used to control the spread of pests like fruit fly but can also be used to kill dangerous bacteria and microorganisms that cause food poisoning, like Salmonella, Campylobacter and E. coli. It can also be used as a way to prolong shelf life of food by slowing down the ripening process and can stop vegetables from sprouting."*[29]

[29] https://www.foodstandards.gov.au/consumer/foodtech/irradiation/Pages/default.aspx

The nuclear industry also spruiks the benefits of shelf-life extension, which is not a permitted purpose for the irradiation of fruit. For example, commercial irradiator Steritech's marketing material on produce irradiation states:

> *"…Phytosanitary Irradiation is becoming the preferred and trusted treatment of Australia's trading partners in markets such as USA, New Zealand and Vietnam. The treatment is a simple wave of energy which passes through the packaging and fruit much like an X-ray. It is capable of treating premium packaged products as well as insects found inside the fruit itself. In the past, both of these scenarios would have been otherwise difficult or impossible to treat using established processes. For high value, highly perishable products such as berries and cherries,* ***the treatment has a notable shelf life and quality advantage when compared to product treated by other means****."*[30]

It is unclear how regulators will ensure that food irradiation is used solely for its lawful purposes once blanket approvals for ALL fruits and vegetables are the norm.

Furthermore, generic irradiation standards provide a range of potentially suitable radiation doses for certain pests or purposes, from 150Gy to 1kGy. There is no process to ensure that the minimum dose is used for all treated products or to test the suitability of a new product for irradiation.

The International Atomic Energy Agency International Database on Commodity Tolerance (IDCT)[31] is a compilation of research on radiation impacts on various fruit, vegetables and flowers, aimed to provide guidance on irradiation doses for specific purposes. The information on approximately 80 fruits and vegetables indicates a breadth of dose-specific impacts on food integrity. For many commodities, there is limited research data available and much of the research pre-dates the identification of residual radiolytic products, and other systemic issues. With scant research data available, there is no mechanism to ensure that industry will determine or use radiation dosages for particular purposes, products, and/or pests.

Approval of A1193 would also facilitate an increase of the trade in irradiated foods, some of which may be pre-packaged. There is no clear regulatory guidance in the Code on irradiated packaging or assurance that packaging will be appropriate to withstand irradiation. Reference to appropriate packaging, which was part of the Code until November 2012, was removed from the Standard. While the Department of Agriculture requires documentation and consideration of packaging in dose determination, there is no guidance on packaging materials – which are also impacted by exposure to radiation. US regulations have clear guidance on appropriate materials within the food code: Irradiation in the production, processing and handling of food.[32]

Australia ought to follow suit.

There is no demonstrated framework for monitoring and enforcement around irradiated fruit and vegetables which are unlikely to be individually labelled. Current irradiation labelling laws are inadequate, but the labelling requirement for packaged goods may make some monitoring possible if systems and personnel were charged with doing so.

[30] https://steritech.com.au/wp-content/uploads/downloads/Steritech_Fresh_Produce_Brochure_Web.pdf
[31] https://nucleus-qa.iaea.org/sites/naipc/IDCT/Pages/default.aspx
[32] https://www.ecfr.gov/cgi-bin/text-idx?SID=a039ae3770875b2505085a2214537653&mc=true&node=pt21.3.179&rgn=div5#se21.3.179_126

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.

> "The department operates a five per cent random surveillance scheme to monitor a range of food imported into Australia for compliance to some standards in the Australia New Zealand Food Standards Code. These tests are applied as part of a rolling program of surveillance on the Australian food supply."[33]

An example is here: https://www.agriculture.gov.au/import/goods/food/inspection-compliance/failing-food-reports/oct2018#random-monitoring-of-food-for-compliance

This random sampling suggests that illegal irradiation is common. Unfortunately, non-packaged irradiated products are more difficult to monitor. The lack of a precise and easy test makes it difficult to assess whether a product has been irradiated or not and, unless labelling is enforced, customers will be none the wiser, as irradiation is an invisible process. Especially if the amount of irradiated food grows exponentially, monitoring and compliance may rely solely on industry disclosure. There is no evidence that the states have the will or capacity to conduct any testing, monitoring or enforcement, even on the limited number of foods already approved.

Failure to Demonstrate a Technological Need

Neither the Applicant nor FSANZ have established a technological need for using irradiation as a quarantine or phytosanitary measure for all fresh fruits and vegetables. A phytosanitary "need" for irradiation has not been proven, as numerous alternative management practices, processes, and technologies already exist for the same purpose.

Australia was the first country to implement irradiation as a phytosanitary measure for trade, exporting mangoes to New Zealand in 2004. Australia soon became the world leader in phytosanitary exports.[34] While the Australian irradiation and import/export food industries have clear motivations to push for irradiation as a phytosanitary measure, it is not the norm world-wide. Our trading partners generally do not require irradiation and it remains the exception rather than the rule.

A trade and marketing justification for irradiation is not proof of a technological need. FSANZ and the applicant both assert that there is a need, but also state that the proportion of irradiated food in the typical diet will be negligible, as most fresh foods are consumed in the quarantine zone where they are produced so do not require phytosanitary treatment. While this may provide a justification for irradiation it does not constitute evidence of a need.

Application A1193 claims that irradiation is necessary to control the transmission of fruit fly, in particular Queensland fruit fly, to encourage greater import and export of foods grown in areas that are potentially fruit fly infested. Though Queensland lodged this application, the Victorian Government has acknowledged that its attempts to contain fruit fly infestations in the state have failed and it has not continued to fund pre-harvest control measures.[35]

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

[34] G.J. Hallman, P. Loaharanu, Phytosanitary irradiation – Development and application, Radiation Physics and Chemistry 129 (2016) p.42 http://dx.doi.org/10.1016/j.radphyschem.2016.08.003

[35] https://www.betterhealth.vic.gov.au/health/HealthyLiving/food-irradiation

The Victorian Government also granted almost five million dollars towards the cost of an irradiation plant being built at the Wholesale Fruit and Vegetable markets in Epping, Melbourne. [3637]
This suggests that irradiation may also become a standard fruit fly control measure throughout Australia if other mitigation and management options remain unexplored.

Irradiation is not an easy substitute for a holistic approach to managing and minimising fruit fly and other pest insects. The Legislative and Governance Forum on Food Regulation (the Forum) has long been derelict in its duty to canvass all potential pre- and post-harvest management, chemical and technical options to follow the final phase-out of toxic fruit fly insecticides. Some post-harvest chemicals in which fruit and veggies were dipped have been phased out because of their toxicity, finally admitted after decades of use. Now irradiation is promoted as an efficient and affordable "alternative" that will give our producers and their products access to pest-sensitive markets. But numerous other non-chemical alternatives also exist, including pre-harvest management – the pheromone strips, bagging etc., that organic growers use - and other methods - heating or cooling, altered atmospheres, etc. - along food supply chains.

International precedents do not justify a need

FSANZ justifies approving A1193 in part "by virtue of consistency with other international regulations on irradiated food". This is misleading. While some countries do have general approvals for the irradiation of fruits and vegetables many others do not and the purposes for which irradiation is approved are diverse. Irradiation as a technology for phytosanitary control is new and has not been widely adopted.

Due to concern about radiolytic products, the European Union continues to limit generic food irradiation approvals to herbs and spices, allowing member states to maintain earlier approvals. Japan only allows the irradiation of potatoes and most other nations still do not accept irradiation as a phytosanitary measure.

Australia's only commercial irradiator, Steritech, claims that its Queensland facility, opened in 2004,

> "was the world's first whole pallet irradiator built for the handling needs of perishable fresh produce and was also the first facility in the world to treat fruit for international export." [38]

The International Atomic Energy Agency (IAEA) names Australia as the first country to use irradiation as a phytosanitary measure in international trade. Eight other countries that also engage in the practice.

Steritech states:

> "Australia has currently established irradiation protocols to seven markets that include USA, New Zealand, Vietnam, Indonesia, Malaysia, Thailand and Cook Islands." [39]

Australia is leading the charge for irradiated produce, to promote the export and import of treated fruits and vegetables, even though much of the produce is consumed here. In 2016, the IAEA reported that 70% of Queensland produce irradiated each year was sold within Australia.[40]

[36] https://melbournemarkets.com.au/about-the-market/overview/
[37] http://www.fruitnet.com/produceplus/article/171684/steritech-coming-to-melbourne
[38] https://steritech.com.au/industries/fresh-produce/
[39] https://steritech.com.au/industries/fresh-produce/
[40] https://www.iaea.org/newscenter/news/new-zealand-can-import-winter-tomatoes-thanks-to-australias-food-irradiation-facility

FSANZ also cites the Codex Alimentarius revised standard on irradiated food (2003) in support of their proposal to approve A1193. However, this Codex document predates the emergence of well-documented cases of serious toxic effects from the consumption of irradiated foods that still remain poorly understood. Furthermore, Codex guidelines permit up to 10kGy as a generic irradiation dose. If Australia falls in line on generic approvals, Australia may push to significantly increase the approved maximum radiation dose of 1 kGy for fresh fruits and vegetables – the dose upon which all current assessments, including health and nutrient assessments and contested claims, are premised.

Numerous alternatives to irradiation could replace phased out toxic chemicals

There are numerous alternatives to irradiation but Australia is leading the push internationally for irradiation to be deployed as a phytosanitary measure. Despite years to prepare for the final phase out of Fenthion and Dimethoate, for example, industry pushed irradiation as the go-to substitute rather than investing in research or setting up pest controls and production practices which would eliminate or lessen the need for post-harvest phytosanitary measures.

Australia was the only country still permitting Dimethoate to be used for post-harvest pest control which tells us that all other markets had found other options. Indeed, the task force phasing out this chemical provided growers numerous chemical alternates to Dimethoate and Fenthion. Of course, non-chemical alternatives, such as organic management systems exist and can be reliably and successfully used for phytosanitary purposes.

Though irradiated tomatoes are accepted for export from Australia to New Zealand, New Zealand quarantine also accepts un-irradiated Australian tomatoes, provided they are grown in pest-free zones, which are already feasible in most states.

While phytosanitary treatments may vary according to desired outcome, some of the alternatives currently in use include:

- Cold storage
- Cold treatment
- Heat/steam, vapour treatment
- Hot water dips
- Atmospheric control with oxygen, carbon dioxide or nitrogen
- Physical disinfestation, i.e. cleaning, washing
- Hygienic and safe production practices
- Pest exclusion zones
- Early harvesting
- Organic production

With numerous chemical-free and irradiation-free options for the production of food, which pose little or no health risk to shoppers and their families, the use of irradiation as a phytosanitary measure primarily to promote and protect markets, is inexcusable**.**

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. At best, it may substitute for one chemical application in post-harvest treatments used to take products to global, pest-sensitive markets. The post-harvest neutralisation of pests through one-off irradiation exposure does not eliminate the use of chemicals, pesticides, genetic manipulation, cold storage, or other processes used on produce from their planting to their consumption

There is little research on the interaction of irradiation with GMOs, pesticides and other chemicals used in agriculture and food supply chains. If the irradiation industry is to expand as it intends, FSANZ must guarantee the safety of such interactions.

International Phytosanitary obligations do not require irradiation

The fact that irradiation is listed as an international phytosanitary measure is not a satisfactory justification or rationale for using irradiation for that purpose. International Standards for Phytosanitary Measures that mention irradiation also identify many other possible phytosanitary technologies and management processes and recommend an integrated systems approach. Irradiation is just one among many possibilities for post-harvest treatment so it would not be the preferred treatment if a suite of the numerous other options were available and used instead. There is no technological imperative or requirement to irradiate foods, nor a situation in which irradiation is the only choice.

> "In principle, systems approaches should be composed of the combination of phytosanitary measures that can be implemented within the exporting country. However, where the exporting country proposes measures that should be implemented within the territory of an importing country and the importing country agrees, measures within the importing country may be combined in systems approaches.
>
> The following summarizes many of the options commonly used:
>
> **Pre-planting**
>
> - healthy planting material
> - resistant or less susceptible cultivars
> - pest free areas, places or sites of production
> - producer registration and training.
>
> **Pre-harvest**
>
> - field certification/management (e.g. inspection, pre-harvest treatments, pesticides, biocontrol, etc.)
> - protected conditions (e.g. glasshouse, fruit bagging, etc.)
> - pest mating disruption
> - cultural controls (e.g. sanitation/weed control)
> - low pest prevalence (continuous or at specific times)
> - testing.
>
> **Harvest**
>
> - harvesting plants at a specific stage of development or time of year
> - removal of infested products, inspection for selection
> - stage of ripeness/maturity
> - sanitation (e.g. removal of contaminants, "trash")
> - harvest technique (e.g. handling).
>
> **Post-harvest treatment and handling**
>
> - treatment to kill, sterilize or remove pests (e.g. fumigation, irradiation, cold storage, controlled atmosphere, washing, brushing, waxing, dipping, heat, etc.)

- inspection and grading (including selection for certain maturity stages)
- sanitation (including removal of parts of the host plant)
- certification of packing facilities
- sampling
- testing
- method of packing
- screening of storage areas.

Transportation and distribution

- treatment or processing during transport
- treatment or processing on arrival
- restrictions on end use, distribution and ports of entry
- restrictions on the period of import due to difference in seasons between origin and destination
- method of packing
- post entry quarantine
- inspection and/or testing
- speed and type of transport
- sanitation (freedom from contamination of conveyances)." [41]

Irradiation facilitates food imports that may harm Australian farmers

While irradiation serves global industrial agribusiness and may facilitate access to some overseas markets, it will just as easily open the floodgates for irradiated imports into Australia and New Zealand.

We question the lack of serious analysis of the claimed benefits of irradiation as a market access tool for producers. This should be weighed against any claimed benefits and costs for shoppers. While irradiation is promoted as unreservedly beneficial to Australian farmers, each approval also enables irradiated imports from overseas, where food may often be cheaper to produce. Irradiation is a tool of large agri-business which supports mass production systems that diminish the power of local food producers and may destroy local markets.

Imports played a key role in the demise of Australia's domestic tomato industry. In 2012, tomato imports were on the rise due to low levels of Australian production, the rising value of the Australian dollar, higher Australian labour costs, and a legal challenge that upheld market access for imports, due to international trade agreements**.** Only 2 out of 10 cans of tomatoes sold in Australia were locally produced.[42]

To increase output and lower production costs, Australia also moved much of its tomato industry to large hothouse-style production, which had devastating impacts on smaller growers and closing Queensland's (and Australia's) largest tomato producer, SP Exports.

[41] Secretariat of the International Plant Protection Convention International standards for phytosanitary measures ISPM 14, The use of integrated measures in a systems approach for pest risk management Adopted 2002; published 2017 © FAO 2017, p 8-9

[42] Fyfe, Melissa and Millar, Royce, Canned: why local tomatoes cop a pasting The Age, May 27, 2012 http://www.theage.com.au/national/canned-why-local-tomatoes-cop-a-pasting-20120526-1zc2q.html

Irradiation was supposed to support the industry by securing access to markets outside Australia. But irradiation could not provide the solution to what was causing the market's demise: market saturation and import competition that large food corporations and supermarket chains had created.

Trade harmonization is a major consideration for the WTO and irradiation proponents. Irradiation was intended to support the expansion of the tomato industry into new markets. But that technology and transportation-intensive market would not have been necessary in the first place, if the local economy, local food manufacturers, and local food security had been prioritised ahead of exports.

Australian food production has a reputation for being clean and green compared to farming elsewhere. International trends show that Australian and overseas shoppers prefer fresh, natural and non-adulterated food of known provenance. Irradiation is a clear step away from this trend.

Labelling, public awareness and engagement inadequacies

All shoppers have the right to access affordable food that is healthy, nourishing and safe. We should not have to choose between potentially toxic and nutritionally depleted food production practices and we must be able to easily recognise whether a product is pure or adulterated, fresh or irradiated.

Despite being a major international issue in the 1980s and a vibrant community campaign in Brisbane/Australia in the early 2000s, there is little customer awareness about food irradiation in Australia and overseas.

Labelling is the only mechanism available that may enable the public to identify whether or not a product is irradiated. Labelling regulations in Australia and New Zealand are inadequate as they do not guarantee clear, accessible, and easily understood information for the public.

The labelling regulations on irradiated fruits and vegetables fail because they do not:

- prescribe mandatory labelling statements that include "irradiation" or "radiation";
- require individual labelling of irradiated food products;
- require that products such as pet food and animal feed are labelled.

They also fail by allowing:

- wording such as "treated with ionizing electrons" which may be technically incorrect;
- wording that does not include "irradiation" or "radiation";
- positive statements that may mislead shoppers;
- the Radura Mark, an international symbol which looks like a budding flower;
- a sign near a point of sale instead of individual product labels.

To adequately inform the public, irradiated foods must be consistently labelled with the prescribed words: radiation, irradiation or irradiated. Wherever practicable, individual labels on bulk foods should be mandated. Required labelling should apply to all irradiated products, whether they are regulated as food, therapeutic goods or agricultural and veterinary products.

Positive statements for marketing purposes are permitted so they 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.

The evidence so far is that FSANZ and irradiation proponents will obfuscate rather than elucidate issues around the safety and efficacy of irradiated foods, and are doing a second-rate job of managing the regulatory process.

Over the 19 years since the first food irradiation approval – for herbs, spices and herbal infusions – the interested public has had to continuously monitor, lobby and contest the FSANZ agenda, seeking to maintain and improve the only means of identifying whether a food has been irradiated or not, by ensuring it is adequately labelled.

In 2012, FSANZ inserted proposed changes to irradiation labelling and record keeping into a Queensland Department of Primary Industries application for approval to irradiate persimmons.

In October 2012, the Federal Court of Australia found that FSANZ had misled the public regarding the content of A1038 for the irradiation of persimmons through providing limited information about the nature of the Application. While it ruled that FSANZ had satisfied its statutory obligations, it had failed to adhere to "the spirit of the Act."[43] The misleading information related to what was easily viewable and accessible on FSANZ's webpage.

Judge Kenny J stated:

> "It should be borne in mind that the object of the Act is to ensure a high standard in public health protection via, amongst other things, achieving the goal of "an affective, transparent and accountable regulatory framework, within which the food industry can work efficiently." The public notice requirements … were presumably intended to promote accountability and transparency in the regulatory framework."[44]

With Application A1193, FSANZ has failed to transparently provide timely information to allow full public engagement. FSANZ did not notify the public that months after A1193 was announced, the applicant – Queensland Government - opted to pay a fee to fast-track the assessment process. Published documents on A1193 continued to suggest that the public consultation period for this application would be scheduled for April 2021. From conversation with FSANZ, it is now apparent that applicants often take up the option to pay for fast-track assessments. FSANZ is required to update the public of such time-table changes but claims that merely altering the dates in its Work Plan is sufficient notice to inform the public. In our view, FSANZ misled the public when it failed to publish enough information so the interested public could fully engage with the consultation process, as the regulator 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, and
- reference or link to the Work Plan, the only place that updated information was posted.

Through communication and conversation with FSANZ we secured a meagre two-week extension for the public consultation period, to December 24, 2020. Yet within that 2-week period, FSANZ has also failed to update its Work Plan to indicate that public comments on A1193 will still be accepted. At time of writing (Monday Dec 21, 2020), the FSANZ Work Plan available on its website has not been updated. It is dated November 17, 2020, and indicates that A1193 submissions have closed. [45]

Furthermore, while the extension was granted and notified in an emailed Notification Circular to subscribers on December 11, the extension was not posted on the A1193 webpage until later, December 16 (as far as we can ascertain). If the FSANZ Work Plan is the go-to document for

[43] Gene Ethics Pty Ltd and Anor v Food Standards Australia New Zealand [2012] FCA 1173, 19 October 2012, p38
[44] Gene Ethics Pty Ltd and Anor v Food Standards Australia New Zealand [2012] FCA 1173, 19 October 2012, p37
[45] https://www.foodstandards.gov.au/code/changes/workplan/Pages/default.aspx

application updates, it should be continuously updated and linked to application websites for the public to view. Anyone seeking information about A1193 would most likely visit and view the A1193 webpage, so all the information needed for a citizen to engage with the application and comment process should be posted there in a prominent and timely way.

Our communications with FSANZ indicate that the unacceptable failure to provide updates directly on an application's webpage is standard practice. There is no avenue for a citizen to know where to look for and find reliable information, leaving the power to engage in the hands of applicants, relevant industries and those with some prior knowledge and engagement with the regulatory system.

In democracies, public consultation processes are intended to provide opportunities for robust engagement with matters that concern the citizenry. FSANZ's notification processes fail to support or facilitate public engagement and must be overhauled to ensure that they begin to do so.

Conclusion: A1193 Must Be Rejected

As a matter of urgency, and in the public interest, we call on FSANZ to reject A1193**.**

Supporting Organisations

Food Irradiation Watch

Food Irradiation Watch is a consumer advocacy network aimed at raising awareness about food irradiation. We work to ensure the consumer's right to choose to avoid irradiated foods, pet foods and therapeutic goods. Food Irradiation Watch works with and advocates for the community on the issue of food irradiation, alternatives to food irradiation, and related food, environment and social justice issues. Food Irradiation Watch is coordinated by Friends of the Earth.

GeneEthics

GeneEthics is a non-profit educational network of citizens and kindred groups. We want the precautionary principle, scientific evidence and the law rigorously applied to all proposed uses of genetic manipulation (GM) technologies and their food and farm products. GeneEthics generates and distributes accurate information and analysis on the ethical, environmental, social and economic impacts of GM and related technologies. Our education programs critically assess GM for the public, policy-makers and interest groups.

Friends of the Earth Australia

Friends of the Earth (FoE) Australia is a federation of independent local groups working for a socially equitable and environmentally sustainable future. Friends of the Earth Australia is part the world's largest grassroots environmental network, uniting 76 national member groups and some 5,000 local activist groups on every continent. Friends of the Earth opposes all forms of the commercial and military nuclear industry and supports sustainable agriculture as the viable alternative to food irradiation.

GM-Free Australia Alliance

The GM-Free Australia Alliance supports this submission. We oppose the irradiation of fresh fruits and vegetables, have concerns about the wholesomeness of irradiated foods and the environmental, social and ethical impacts of food irradiation. Better alternatives to irradiation exist. Irradiation of fruits and vegetables does not benefit Australians.
www.gmfreeaustralia.org.au

Australian Food Sovereignty Alliance

We aim to continuously adapt and improve the ongoing development of the LDF by remaining transparent and open to suggestions from our members and from the broader public. The LDF aims to identify and act on emerging legal issues and trends in Australia and overseas relevant to food sovereignty, and do so by building strong and productive relationships with stakeholders.

APPENDIX 1: Application A1193 Unresolved Questions

The text of the Queensland Government's application A1193, for the irradiation of ALL fresh fruits and vegetables, raises many unresolved questions. We pose these questions to FSANZ and anticipate their answers will be published, in fulfilment of their duty to regulate foods in the public interest.

1. A phytosanitary measure is required whenever commodities are subject to a mandatory treatment to ensure freedom from regulated pests.

Q: Is this statement of purpose circular and therefore tautological?

2. Irradiation at doses between 150 Gy and 1 kGy is a highly effective phytosanitary measure… well suited to assist in expanding market access, both export and import.

Q: Is expanding market access a legitimate ground for FSANZ granting A1193 approval? Given the wide range of potential exposures, who will decide the appropriate exposure for each category of fruits and vegetables? On what grounds will these levels be set and to whom are they answerable?

3. There is a range of treatments that may be used as phytosanitary measures… based on treatments that are physical (cold, heat) or chemical (fumigation, insecticide) or, in limited cases, a systems approach including in-field insecticides, non-host status or area freedom.

Q: Why does the applicant claim that a systems approach is limited? Does FSANZ agree that preventing contamination is superior to requiring phytosanitary decontamination?

4. It is a chemical-free treatment resulting in no harmful treatment residues on the produce.

Q: Does the formation of radiolytic products in irradiated produce refute this assertion?

5. Vietnam (mango, litchi) and India (mango) have begun exporting irradiated fruit to Australia.

Q: Were these irradiated imports labelled as such when sold in Australia?

6. Australia exports more than 90 fresh fruit and vegetable products to more than 60 countries.

Q: If A1193 were approved, what are the estimates of the quantities of irradiated produce likely to be imported into Australia?

7. … industries choose a phytosanitary treatment governed solely by which option is optimal, based on effectiveness, quality retention and cost.

Q: Who will monitor and ensure compliance with the sole purpose of phytosanitary insect treatment? On the basis of these criteria, what is the justification for the claim made elsewhere that irradiation will not be used much?

8. The use of insecticides is being increasingly restricted and irradiation provides a replacement option.

   Q: Why is irradiation regarded as a replacement for insecticides as several other options are available?

9. All the countries that are presently trading in irradiated fruits and vegetables approve phytosanitary irradiation for all fruits and vegetables.

   Q: Why is data from the commercial experience of Australia, NZ and these other countries not part of the supporting evidence for this application and the supporting document?

10. The Codex General Standard (CAC 2003a) treats irradiation as any other food process that is safe and nutritionally adequate for any food.

Q: If irradiation is safe and nutritionally adequate for any food, why are dried pulses, legumes, nuts and seeds excluded from the application?

11. ISPM 28 Appendix 7 recognises 150Gy as the dose to guarantee sterility, preventing adult emergence, of all fruit flies in all hosts.

    Q: On what basis do the applicant and FSANZ justify an application for a maximum dose of 1 kGy when a dose of 150Gy guarantees the sterility of all fruit flies in all hosts? Who makes the decision on the level of radiation energy to be applied to any particular produce consignment, what are the procedures, technical requirements and produce sampling criteria on which that decision would be based?

12. In future, a dose of 400 Gy is expected to become the recognised world standard for phytosanitary treatment of all insects in all host fruits and vegetables except pupae and adult *Lepidoptera*.

    Q: If this were so, how would the application for a maximum of 1 kGy be justified?

13. Irradiation processing costs are comparable to alternative post-harvest physical and fumigation treatments; insecticide treatments will be cheaper and vapour heat treatments more expensive (Loaharanu 2003). Other treatments are of comparable cost (Hallman 2011). MeBr treatment costs will rise as MeBr reduction or recapture technologies are required.

    Q: The references for these assertions are long out of date, so what are the present relative

costs of various treatments and how do they compare with the present $170/tonne average cost at the Steritech facility?

14. A generic approval will not mean the unjustified use of irradiation. … All phytosanitary treatments are authorised under established protocols between national or state plant protection agencies.

    Q: Is this assurance consistent with the applicant's claim that "choice will be based solely on effectiveness, quality retention and cost"?

15. … generic) approval of phytosanitary irradiation will also be beneficial to both government and industry through a reduction in regulatory and management costs.

    Q: Do plant protection agency protocols include monitoring, compliance, enforcement and accountability provisions? Do they have any responsibilities for public health, safety and wellbeing?

16. The percentage of the imports that is likely to switch from an existing treatment to irradiation (G. Robertson, Steritech, *private communication)*; this percentage was estimated conservatively (i.e., was likely to be an over-estimate)

    Q: Did the applicant and Steritech supply any credible data to justify this claim, especially as the company would likely seek to maximize the use of its facilities, ahead of other treatments?

17. FSANZ (2014b) concluded that phytosanitary doses of irradiation: • Do not decrease vitamin C levels in the majority of fruits and vegetables;

    Q: Does 'majority' mean 51% or 99%, and does FSANZ offer more precise data?

18. FSANZ also concluded that

    - As a result of the more limited data available for fresh vegetables, particularly roots and tubers, leafy vegetables, brassicas and legumes, there remained some uncertainty about the effects of phytosanitary doses on fresh vegetables.
    - Data would be required on vitamin E, thiamine and non-bioactives if present at high levels and making an important contribution to dietary intake.

    Q: Is detailed data now available to resolve these uncertainties and, if so, where is it published?

19. In the general population, the proportion of the intake of radiation-sensitive micronutrients derived from fresh fruits and vegetables that will be irradiated is less than 2% for vitamin C and less than 1% for vitamins A, E and thiamine;

    Q: Did the applicant submit any detailed data on sub-groups in the general population, such as: vegetarians; vegans; cultural sub-groups; socio-economically disadvantaged people; children;

the elderly; etc.?

20. Of more interest to this Application is the significant number of countries that approve phytosanitary irradiation for all fruits and vegetables.

    Q: What does 'significant number' mean in this context?

21. A second food irradiation facility being constructed in Melbourne is an X-ray facility.

    Q: What is the current operational status of the facility, where is it located, and when will it be commissioned?

22. The amount of irradiated produce available within Australia has been under 100 tonnes per year. There have been no protests or negative publicity regarding irradiated fruit on the Australian domestic market.

    Q: Where was the irradiated fruit sold on the Australian domestic market, was it labelled as the law requires, and, if so, were surveys or education conducted to gauge shopper reactions to the signage and the products?

23. A phytosanitary measure is required whenever commodities are subject to a mandatory treatment to ensure freedom from regulated pests.

    Q: Who is qualified and authorised to mandate any phytosanitary treatment? Are there any appeal processes against such mandatory treatment?

24. The requested amendment would provide the horticulture industry with a phytosanitary option that is justified due to a technical need to provide a superior quarantine treatment better suited to the present trading environment.

    Q: Is there evidence that irradiation is a 'superior quarantine treatment' when compared with other methods? As there are several other effective phytosanitary systems available, what evidence is there that irradiation is 'justified due to a technical need"?

25. Only a small fraction is likely to be irradiated.

    Q: Is this claim justified as the applicant and Steritech clearly intend to promote irradiation as the 'superior' option of choice?

26. … a penetrating treatment … with no 'dead' spots.

    Q: Is radiation exposure uniform throughout a treated shipment and is its effectiveness dose dependent?

27. A generic approval for phytosanitary irradiation of all fruits and vegetables will not mean the unjustified use of irradiation for any commodity. Standard 1.5.3 requires irradiation of fruits and vegetables to be for a phytosanitary purpose. … There is no incentive for the industry to use irradiation unnecessarily.

    Q: Who are the judges of whether a treatment is justified or not? As microbial contamination is also treated and shelf–life is extended when produce is irradiated, what practical and routine processes exist to ensure that insect de-infestation is the sole purpose for such treatments? Are these collateral benefits of treatment not also incentives to use irradiation?

28. There are reports that they (shoppers) may be more concerned about such residues than irradiation though their willingness to pay for more residue-free food varies (Baker and Crosbie 1993, Baker 1999, Gamble, Harker and Gunson 2002).

    Q: Is this another example of the applicant submitting out of date evidence?

29. The mandatory labelling requirements for irradiated produce allows consumers to make informed choices.

    Q: Though labels are mandatory, what data shows that the requirement is being monitored and enforced?

30. We question the applicant's assertions that

    - irradiated fresh produce will remain a minor part of the overall diet,
    - the percentage of key micronutrients derived from fresh produce that will be irradiated will be very low, and
    - phytosanitary doses do not have significant adverse effects on these key micronutrients.
    - The risk of an adverse nutritional impact on Australian and New Zealand consumers from approving phytosanitary irradiation for all fresh produce is negligible.

    Qs:

    - In light of the commercial, trade and marketing forces in play, what evidence exists that irradiated produce will remain a 'minor part of the overall diet'?
    - What epidemiological, dietary survey, or other data supports the claim that the % of key micronutrients affected 'will be very low'?
    - In what sense is 'significant' used here?
    - What evidence confirms that adverse nutritional impacts from approving irradiation of 'all fresh produce is negligible'

31. FSANZ concluded that
    - Doses no greater than 1 kGy would not adversely affect dietary vitamin C and carotene

intakes from all fruit.

Q: Where is the published evidence from tests on 'all fruit', to confirm that 'dietary vitamin C and carotene intakes' are not adversely affected?

32. Tables 7 and 8 show the percent of nutrient intake without the potential for all fruits and vegetables in the diet to be irradiated.

    Q: What would the data be expected to show if all fruits and vegetables were irradiated? How will the expected changes from such irradiation affect the efficacy of programs that promote greater fruit and vegetable consumption in the interests of public health, wellbeing and disease prevention, for the whole community?

33. Perhaps irradiated green and fruiting vegetables could total 2,500 tonnes out of a total of 846,000 tonnes of total vegetables (0.3%).

    Q: Is this a realistic estimate? As irradiation technology's owners will seek greater business opportunities, to what extent will approving A1193 facilitate their equipment being used more?

34. Tables 11 and 12 contain estimates that the irradiation technology owners supplied or commissioned.

    Q: Who peer-reviewed the estimates? Are the estimates valid as the irradiation technology owners have a clear conflict of interest? Can present levels of irradiation, on a limited range of fruits and vegetables, be reliably extrapolated to future use?

35. Table 13 Assumptions.

    Q: On what basis are these assumptions made and justified? Do they take into account future irradiation if all fruits and vegetables were approved for irradiation?

36. The estimates, which are very approximate …

    Q: Are they an adequate basis for big decisions, which may have substantial impacts on the capacity of the fresh food supply to deliver the health, wellbeing and illness prevention that the public expects?

37. These percentages have been conservatively estimated and could possibly be significantly lower.

    Q: In the preparation of the application, were any statisticians, nutritionists or other key expert personnel consulted? Why was additional data not sought to validate the applicant's estimates and assumptions?

38. These data are of variable quality but are presented as they are generally consistent with the FSANZ conclusion that micronutrient changes from doses up to 1 kGy are not significant for these types of commodity.

Q: Is this an example of a convenient consensus based on questionable data? Is an applicant's reliance on the regulator's own report acceptable regulatory practice, where independence and objectivity should be vested in the critical scrutiny that independent experts and the public can provide?

39. Leafy greens - spinach and fenugreek; lettuce; other. Brassicas – cauliflower; cabbage. Roots and tubers – carrots; sweet potato; potato. Fruit and vegetable juices.

Q: Is this subset of fresh fruits and vegetables proposed to be a representative sample of all those commercially available and likely to be irradiated?

40. We conclude that the risk of an adverse nutritional impact from approving phytosanitary irradiation for all fresh produce is of no practical concern.

Q: What level of 'adverse nutritional impact' would be of 'practical concern'?

41. 3.2. Toxicological data.

Q: Most evidence cited in this section is decades old, so why has it not been superseded, especially with data from real world, commercial experience with millions of people?

42. Furan, a genotoxic carcinogen, … has been detected in some fruits irradiated at 5 kGy but not in any vegetable tested. … 2008). The maximum dose for phytosanitary irradiation (1 kGy) is five times lower and furan levels, if produced, are likely to be at undetectable levels generally considered not high enough to have a toxicological effect.

Q: Can the applicant justify an assumption that lower radiation doses will reliably produce less furans? Is there evidence that furans, 'if produced, are likely to be at undetectable levels'? What authorities 'generally considered' that furans would not be high enough to have a toxicological effect?

43. Possible furan production does not appear to be a realistic risk following phytosanitary irradiation (EFSA 2011a).

Q: Is it appropriate to base such an assertion on a Scientific Opinion rather than a published and peer-reviewed research paper, particularly as it is sanguine that "no in vivo genotoxicity studies are available" and that "Concerning other radiolytic products no new relevant toxicological studies (genotoxic, subchronic, carcinogenic/chronic, reproduction) have been reported"?

44. Pet food

Q: Is it sufficiently precautionary to dismiss the serious neurological defects induced in cats fed dry irradiated pet food? What experiments have been conducted in other species, to determine if the effect is species-specific?

45. 3.4. Microbiological data

    Not relevant to the request for a phytosanitary purpose.

    Q: As microbial sterilisation and extended product shelf life are collateral consequences of phytosanitary de-infestation, is it appropriate for the applicant to ignore them?

46. AS2070 –1999 … includes such items as packages, domestic containers, wrapping materials, utensils or any other plastics items intended for food contact applications (SA1999).

    Q: As this Standard predates the commercial irradiation of foods, does it provide any assurance that leaching from or degradation of materials in contact with irradiated fresh fruits and vegetables does not occur? Does any experimental evidence exist to resolve this question?

47. Codex accepted the JECFI conclusions and its recommendation stated that "any food irradiated up to an overall dose of 10 kGy is safe and wholesome".

    Q: But should the applicant have also cited the JECFI's further recommendation that "attention should be given to the significance of any changes in relation to each particular irradiated food and to its role in the diet; this implied that in clearing foods treated by irradiation up to this average dose, proof should still be required to ensure that, in each case, no microbiological and nutritional changes were introduced by the process of irradiation and that populations consuming diets containing irradiated foods should be monitored for nutritional adequacy"?

48. … approval of phytosanitary irradiation will result in reductions in pesticide use and disposal, storage of postharvest insecticides on-farm and reduced workplace health safety issues.

    Q: As a matter of public policy, does the Queensland Department of Agriculture fail to promote pre-harvest fruit fly minimization and management strategies on farm, adopting post-harvest phytosanitary treatment of fruit fly infestations instead? Does this promote fruit fly clean up rather than prevention, in ways that will promote irradiation and expansion of the industry beyond the claimed projections of future uptake?

49. The mandatory labelling of irradiated fruit and vegetables provides consumers with choice when it comes to purchasing or not purchasing irradiated fruit and vegetables.

    Q: Is helping shoppers to make informed decisions about their food purchases more important than having choice, as A1193 could reduce or eliminate the choice of buying un-irradiated fruits and vegetables?

50. 5.2. Consumer acceptance

    Q: As the references cited in this section are mostly old and the information dated, why have the applicant, other governments or agencies not commissioned more recent shopper surveys or other research? Are FSANZ, the governments and industry indifferent to the public's legitimate concerns over the blanket approval of all fruits and vegetables?

51. Commodity tolerance

    Irradiation has an advantage over other phytosanitary treatments in that more types of fresh fruit and vegetables tolerate irradiation than any other commercially available phytosanitary treatment.

    Q: Why does the applicant seek approval to irradiate ALL fresh fruits and vegetables when it is known that some do not tolerate irradiation well?

52. Table: Recent data on effects of radiation on leafy greens, brassicas and roots and tubers

    Q: Should the results of those studies that irradiated samples at doses far outside the proposed range of approved doses be discarded?

53. Significant – how important?

    Q: Though the word 'significant' is used over 90 times in the application, why is it most often used as a mere opinion that some claim is important and rarely to assess the results of formal comparisons of observed data with an hypothesis, to confirm that its truth and robustness have been rigorously assessed?

APPENDIX 2: FSANZ SD1 Questions

The text of the FSANZ Supporting Document for application A1193 - the irradiation of ALL fresh fruits and vegetables – reads more like an advocacy document than an objective and dispassionate scientific evaluation. Even the Executive Summary raises many unresolved questions. We therefore pose these questions to FSANZ and anticipate their answer to be published, in fulfilment of their duty to regulate foods in the public interest.

1. A1193 permission would apply to both domestically produced and imported fruit and vegetables requiring a phytosanitary treatment.

   Q: What are the objective criteria and procedure for a decision that treatment is required or not required?

2. Irradiation as a phytosanitary measure is not a substitute for good hygienic, manufacturing or agricultural practices.

   Q: Who will monitor the supply chain to ensure that standards are maintained throughout production and supply chains, so that the use of irradiation and other de-infestation treatments are minimised and used only when necessary?

3. On the basis of the available evidence there are no safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated with doses of up to 1 kGy.

   Q: Why does FSANZ rely on evidence, much of which is ad hoc, incomplete and not up to date? Many of the tests measure the impacts of radiation exposure outside the doses that A1193 proposes to permit. Over 150 different varieties of tropical fruits are grown in Tropical North Qld alone, yet few have ever been tested for the impacts of irradiation.

4. There is no evidence to indicate that phytosanitary irradiation at the proposed doses would increase the allergenicity of food, or increase the toxicity associated with any mycotoxin contamination.

   Q: Is this a case of evidence of absence masquerading as absence of evidence? What evidence did the applicant and/or FSANZ review before making this absolute claim, as even one example will refute it?

5. FSANZ “decided that the minor nutrient losses caused by irradiation were not a concern for public health.’

   Q: As A1193 greatly increases the scope and scale of the irradiation of fresh fruits and vegetables, what is the evidence supporting this conclusion? Does the decision apply to the diets of all of Australia’s and NZ’s diverse cultures, communities and socio-economic groups?

6. Vitamin A (retinol) which is highly sensitive to irradiation was excluded from the nutritional assessment because retinol is not present in plant foods.

   Q: Why has FSANZ not fact-checked this false statement?

7. Thiamin and vitamin E, also highly sensitive to irradiation, were considered but a firm judgment about the extent of irradiation-induced losses is not made because too few relevant studies were identified.

   Q: Why is the applicant not required to provide adequate evidence?

8. Concern about the absence of evidence for thiamin and vitamin E is obviated by the fact that vegetables make only a relatively small contribution to population intakes of thiamin (less than 10%) and vitamin E (10 – 17%).

   Q: To which population does this claim refer? What is the status of thiamin and vitamin E if fresh fruit?

9. FSANZ considers that based on the available evidence the effect of irradiation on the micronutrient content of fruit and vegetables is likely to be low.

   Q: How does FSANZ justify a decision based on two assumptions, not good evidence – that the 'available evidence ' is relevant and sufficient, and that irradiation's effect 'is likely to be low'?

10. However, there will only be a relatively small proportion of both imported and domestically produced fruit and vegetables in Australia and New Zealand treated by irradiation

    Q: This does not accord with industry's future projections? When, where and by whom will the commercial application of irradiation to ALL fruits and vegetables be reassessed and any necessary changes made.

11. On the basis of the available evidence FSANZ concludes 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.

    Q: How will new and emerging evidence be systematically monitored and necessary changes made to the approval? What are the reporting requirements associated with the proposed approval?