

Appendix 4: Food Irradiation Watch/Gene Ethics questions on the application and SD1 and FSANZ response

The following table contains FSANZ's detailed responses to a list of questions attached to a joint submission from Food Irradiation Watch/Gene Ethics. Specifically, there were 53 questions relating to various aspects of the application and 11 questions relating to SD1 of the CFS report. A high level summary of the main issues raised by submitters and FSANZ's responses is provided at Table 3 of the Approval Report.

Issue and question	FSANZ response
Questions from Food Irradiation Watch/Gene Ethics regarding the application	
<p>1. A phytosanitary measure is required whenever commodities are subject to a mandatory treatment to ensure freedom from regulated pests.</p> <p>Q: Is this statement of purpose circular and therefore tautological?</p>	<p>No.</p>
<p>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.</p> <p>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?</p>	<p>In relation to the question about expanding market access, FSANZ must assess this application in accordance with the FSANZ Act. As explained in Section 6 of this report, the 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.</p> <p>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.</p> <p>Regarding exposures, 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 may be impaired. These values are determined through experience and experimental data, and help define Good Irradiation Practice (GIP) for food, which is an integral part of Good Manufacturing Practice (GMP).</p> <p>For this application, the dose range remains consistent with what is currently approved in Standard 1.5.3 i.e. 150 Gy to 1 kGy. Within that range, there are generic minimum doses for various regulated pests (e.g. 150 Gy for fruit flies) – these are set out via the Interstate</p>

Issue and question	FSANZ response
	<p>Certification Assurance (ICA) Scheme under Operational Procedure Number 55 (ICA-55). As irradiation does not deliver a uniform dose throughout the pallet, to ensure that every area of the pallet receives the minimum effective absorbed dose, other regions of the pallet will receive a higher dose than the minimum (but still under the approved maximum of 1 kGy). Control of dose is managed by accurate dosimetry and maintenance of records under the requirements of Standard 1.5.3.</p> <p>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.</p> <p>Regarding to whom they are answerable, 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.</p> <p>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.</p>
<p>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.</p> <p>Q: Why does the applicant claim that a systems approach is limited? Does FSANZ agree that preventing contamination is superior to requiring phytosanitary decontamination?</p>	<p>A systems approach is limited for the following reasons:</p> <ul style="list-style-type: none"> • it is not accepted by all Australian states (e.g. ICA-26¹) or for international exports; and • it is not approved for all fruit fly species. <p>Regarding other systems approaches such as ICA-28² for citrus, this is only approved for specific regions and harvest dates, and is not approved for interstate trade to Western Australia.</p> <p>It is not FSANZ's role to determine whether preventative or treatment options for pest control in horticulture are superior. This is the decision of individual growers, based on their own assessment of effectiveness and cost.</p>
<p>4. It is a chemical-free treatment resulting in no harmful treatment residues on the produce.</p> <p>Q: Does the formation of radiolytic products in irradiated produce refute this assertion?</p>	<p>FSANZ states that the irradiation treatment is chemical-free, not that no radiolytic products are formed. FSANZ has concluded that the residues are not harmful – see Section 3 (Hazard Assessment) of SD1. The conclusion is that there are no public health and safety concerns relating to the use of irradiation for its proposed purpose. This assessment included an analysis of radiolytic compounds formed by irradiation of fruits and vegetables.</p>
<p>5. Vietnam (mango, litchi) and India (mango) have begun exporting irradiated fruit</p>	<p>Foods imported into Australia or New Zealand must comply with the Code, including the</p>

¹ ICA-26 Pre-harvest treatment and post-harvest inspection of tomatoes, capsicums, chillies and eggplant.

² ICA-28 Pre-harvest treatment (bait spraying) and inspection of citrus.

Issue and question	FSANZ response
<p>to Australia.</p> <p>Q: Were these irradiated imports labelled as such when sold in Australia?</p>	<p>labelling requirements for irradiated foods.</p> <p>Monitoring, compliance and enforcement against the requirements of Standard 1.5.3 is not the responsibility of FSANZ; rather, it is the responsibility of the relevant Australian and New Zealand enforcement agencies.</p>
<p>6. Australia exports more than 90 fresh fruit and vegetable products to more than 60 countries.</p> <p>Q: If A1193 were approved, what are the estimates of the quantities of irradiated produce likely to be imported into Australia?</p>	<p>The submitter refers to a statement made in the application regarding Australian exports, yet the question is about imports.</p> <p>The applicant has provided an estimate of 3% of total fruit and 1.2% of total vegetables consumed in Australia will be irradiated if Standard 1.5.3 is amended to allow phytosanitary irradiation of all fresh fruit and vegetables. This is a conservative estimate meaning it is the greatest proportion of irradiated fruit and vegetables that may be consumed. In answer to the submitter's question, from the data in the application, overseas imports would make up only a small proportion of these amounts. No evidence to the contrary was provided by submitters (including the relevant biosecurity agencies) or located by FSANZ.</p> <p>The Department of Agriculture, Water and the Environment (DAWE) regulates the importation of food into Australia.</p>
<p>7. ... industries choose a phytosanitary treatment governed solely by which option is optimal, based on effectiveness, quality retention and cost.</p> <p>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?</p>	<p>In response to the first question, monitoring and enforcement of compliance with Code requirements is the responsibility of the jurisdictions.</p> <p>In terms of the second question, the majority of produce produced in Australia and New Zealand does not require a phytosanitary treatment because it is produced and consumed within the same quarantine jurisdiction (i.e. state/territory or, for New Zealand, country). Additionally, for many vegetables, an end point phytosanitary treatment is unnecessary because of the harvesting and processing requirements which result in soil and pest free commodities.</p> <p>As such, this permission is likely to apply only to a proportion of produce available to Australians and New Zealanders that is not grown and consumed in the same quarantine region, depending also on its suitability for irradiation and the availability of other existing treatments. For such produce, industry will choose the best treatment option, with irradiation being only one of a number of options.</p> <p>Table 9 of the application shows that the domestic use of irradiation on produce in Australia has been negligible to date. Among the reasons are that irradiation is only used when there are no alternatives or when there has been a suspension of a traditional treatment and, up until recently, with the only irradiation facility based in Queensland it is difficult to fit in to the supply chain for out-of-state produce.</p>
<p>8. The use of insecticides is being increasingly restricted and irradiation provides</p>	<p>Use of irradiation on fresh fruit and vegetables will not be mandatory and is only one of a</p>

Issue and question	FSANZ response
<p>a replacement option.</p> <p>Q: Why is irradiation regarded as a replacement for insecticides as several other options are available?</p>	<p>number of existing phytosanitary treatment options from which the horticultural industry may choose, depending on their individual circumstances.</p>
<p>9. All the countries that are presently trading in irradiated fruits and vegetables approve phytosanitary irradiation for all fruits and vegetables.</p> <p>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?</p>	<p>The application contains data on the quantities of irradiated produce Australia exports (Table 1) the amount consumed domestically (Table 9), and estimates on the amount of irradiated fruit consumed in NZ (from imports).</p>
<p>10. The Codex General Standard treats irradiation as any other food process that is safe and nutritionally adequate for any food.</p> <p>Q: If irradiation is safe and nutritionally adequate for any food, why are dried pulses, legumes, nuts and seeds excluded from the application?</p>	<p>The applicant did not apply to include dried pulses, legumes, nuts and seeds within the scope of their application and therefore these foods were not part of FSANZ's assessment and the proposed changes to the Code.</p>
<p>11. ISPM 28 Appendix 7 recognises 150Gy as the dose to guarantee sterility, preventing adult emergence, of all fruit flies in all hosts.</p> <p>Q: On what basis do the applicant and FSANZ justify an application for a maximum dose of 1 kGy when a dose of 150 Gy 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?</p>	<p>The application is consistent with the present Standard 1.5.3 which provides a dose range for phytosanitary treatments of 150 Gy to 1 kGy. The maximum absorbed dose of 1 kGy is consistent with the maximum set by most other countries that have a phytosanitary irradiation regulation (Thailand sets a maximum of 2 kGy). Phytosanitary treatments deal with insects other than fruit fly, and some require a higher minimum dose than 150 Gy.</p> <p>Irradiation does not deliver a uniform dose throughout the pallet. The area of the pallet receiving the lowest absorbed dose is identified prior to treatment. By ensuring this area receives the minimum absorbed dose guarantees the treatment will be effective (i.e. other regions of the pallet will receive \geq the minimum dose). For example, for fruit flies, if the minimum dose required is 150 Gy then the maximum dose received may be up to 300 Gy. For other regulated pests a higher minimum dose may be required and a small part of the pallet will receive a maximum dose closer to 1 kGy. Optimal dosages for specific commodities are determined through experience and experimental data.</p> <p>All facilities used for phytosanitary irradiation are accredited by their own national plant protection organisations (NPPO) and may also be audited by the NPPOs of importing countries. The role of the NPPO is to ensure that the equipment, as installed and properly operated, consistently performs as expected and that treatment parameters can be met. The NPPOs are also responsible for determining the minimum absorbed doses to prevent and control the introduction of plant pests.</p> <p>See also response to Q2.</p>
<p>12. In future, a dose of 400 Gy is expected to become the recognised world</p>	<p>See response to Q2 and Q11 and Section 2.5.1 of SD1.</p>

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<p>standard for phytosanitary treatment of all insects in all host fruits and vegetables except pupae and adult <i>Lepidoptera</i>.</p> <p>Q: If this were so, how would the application for a maximum of 1 kGy be justified?</p>	
<p>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.</p> <p>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?</p>	<p>FSANZ contacted the Office of Best Practice Regulation (OBPR) to confirm that the standing exemption for applications seeking permission to irradiate foods (reference 13845) still applies in this case given the wider scope than past irradiation applications. The OBPR confirmed that a Regulatory Impact Statement (RIS) was not required as the application appears likely to have only a minor economic impact (OBPR reference number 42788). Therefore, there is no requirement on the applicant to submit extensive cost data to compare the range of treatments available as part of a RIS.</p> <p>Nonetheless, the applicant did provide a summary of a range of treatment options in Appendix 1. Post-harvest treatment with insecticide is estimated to be \$1 per tonne. No estimates on the cost of cold and heat treatments could be made as there is currently no businesses in Queensland registered to use these treatments. This would indicate that industry does not consider these treatments as economically viable alternatives for sales on the domestic market.</p> <p>The relative costs of treatment options will not directly impact on FSANZ's assessment of the application. For produce that does need to apply phytosanitary measures to access export markets, industry will choose the best treatment options for their business based on effectiveness, quality retention and cost.</p>
<p>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.</p> <p>Q: Is this assurance consistent with the applicant's claim that "choice will be based solely on effectiveness, quality retention and cost"?</p>	<p>FSANZ is of the view that the applicant's assurance and claim is not at odds. Industry will choose the best treatment options for their business based on effectiveness, quality retention and cost, within the scope of the permissions set out in Standard 1.5.3 and in accordance with the requirements of the relevant NPPOs and other regulatory agencies.</p>
<p>15. ... generic) approval of phytosanitary irradiation will also be beneficial to both government and industry through a reduction in regulatory and management costs.</p> <p>Q: Do plant protection agency protocols include monitoring, compliance, enforcement and accountability provisions? Do they have any responsibilities for public health, safety and wellbeing?</p>	<p>See response to Q5. FSANZ cannot comment on the scope of enforcement agency responsibilities.</p>
<p>16. The percentage of the imports that is likely to switch from an existing treatment to irradiation (G. Robertson, Steritech, <i>private communication</i>); this percentage was estimated conservatively (i.e., was likely to be an over-estimate)</p>	<p>FSANZ is of the view that the applicant and Steritech supplied credible data in Part 3 of the application and the associated tables. This section of the application provides data on current and projected levels of irradiated produce available for consumption, for both</p>

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<p>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?</p>	<p>domestically produced and imported goods.</p> <p>The data on import volumes and consumption in tables 11-13 were put together from official statistics on agricultural production and trade by an independent consultant (Appendix 6).</p> <p>The applicant makes clear that the figures on the volumes or percentages that could be irradiated are estimates only. The assumptions are provided in Table 11 (New Zealand) and Table 13 (Australia). The estimates and assumptions have been made by the applicant based on their expertise in phytosanitary treatments and commodity trade in general and in consultation with Steritech who are the only company with practical knowledge of phytosanitary irradiation treatments in Australia. The estimates are not based on present or future irradiation capacity, but on the likely choices that growers and traders may make in selecting between potential treatment options. The estimates are thought to be conservative, that is, to over-estimate the potential use of irradiation.</p> <p>FSANZ considered the data and information provided in Part 3 of the application as part of the nutrition risk assessment and, in particular, to determine whether the irradiation of fresh fruit and vegetables (at the estimated volumes and requested dose) would have an impact on population dietary intakes of irradiation sensitive nutrients (see Section 5 of SD1). FSANZ concluded that the impact on population nutrient intakes from consuming irradiated produce would be minimal.</p>
<p>17. FSANZ (2014b) concluded that phytosanitary doses of irradiation: • Do not decrease vitamin C levels in the majority of fruits and vegetables;</p> <p>Q: Does 'majority' mean 51% or 99%, and does FSANZ offer more precise data?</p>	<p>There is no simple percentage to answer this question. FSANZ (2014b) examined effects of irradiation on vitamin C levels in a wide range of fruit and vegetables (pome, stone, berry, citrus and tropical fruits, cucurbits and fruiting vegetables), and this included different varieties of the same plant, different environmental conditions and different handling conditions.</p>
<p>18. FSANZ also concluded that</p> <ul style="list-style-type: none"> • 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, thiamin and non-bioactives if present at high levels and making an important contribution to dietary intake. <p>Q: Is detailed data now available to resolve these uncertainties and, if so, where is it published?</p>	<p>FSANZ confirms that these categories were not considered as part of the 2014 FSANZ review. Therefore, an assessment of the evidence relating to roots and tubers, leafy vegetables and Brassicas was undertaken in Section 4 of SD1. Legumes are not being considered in the application and were therefore not assessed.</p> <p>In response to the submitter's question, the evidence is limited for the effect of irradiation (up to 1 kGy) on the thiamin and vitamin E content of fruit and vegetables. Thiamin concentrations were 6-17% lower in irradiated potatoes – based on results from two studies. The results of one study showed no change in vitamin E content of irradiated leafy vegetables. Concern about the limited amount 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%)*.</p> <p>* Some of the vitamin E comes from fats and oils used during cooking and potato based snack foods.</p>

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<p>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;</p> <p>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.?</p>	<p>The applicant did not submit data on specified subgroups in the general population. The relevant data supplied by the applicant were: Percentage of total vitamin intake that could be irradiated for Australians (aged 2+) and New Zealanders (aged 15+) (in Table 15 on page 42); percent contribution to micronutrient intake from all fruit and vegetables (Table 7, page 33 of the application); and percent contribution of various fruit and vegetable classes to micronutrient intake of Australians aged 2 and over (Table 8 page 34 of the application).</p>
<p>20. Of more interest to this Application is the significant number of countries that approve phytosanitary irradiation for all fruits and vegetables.</p> <p>Q: What does 'significant number' mean in this context?</p>	<p>FSANZ cannot comment on how the applicant has chosen to define 'significant number' in this context.</p> <p>See response to Q53.</p>
<p>21. A second food irradiation facility being constructed in Melbourne is an X-ray facility.</p> <p>Q: What is the current operational status of the facility, where is it located, and when will it be commissioned?</p>	<p>This question is out of scope of FSANZ's assessment of the application.</p>
<p>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.</p> <p>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?</p>	<p>Table 12 of the application shows estimates of volumes of produce imported from overseas or inter-state and liable to be given a phytosanitary treatment. For domestic trade, this is mainly between the exporting states Queensland and Victoria and the fruit fly free importing states of South Australia, Western Australia and Tasmania.</p> <p>A mandatory requirement for produce irradiated for the domestic market (ICA-55) is that treated commodities must be labelled and comply with Standard 1.5.3. As previously mentioned, enforcement, including correct labelling, as well as monitoring and compliance surveys, are generally the responsibility of the relevant Australian and New Zealand enforcement agencies.</p> <p>The most recent consideration of consumer reactions to irradiated foods was examined under FSANZ's response Labelling Review Recommendation 34: Review of mandatory labelling of irradiated food. FSANZ commissioned the Centre for Health Economics and Research Evaluation (CHERE), University of Technology Sydney to undertake a comprehensive literature review of the available peer reviewed literature and relevant grey literature on the responses of consumers to food irradiation labelling. https://www.foodstandards.gov.au/consumer/labelling/review/Pages/default.aspx.</p>
<p>23. A phytosanitary measure is required whenever commodities are subject to a mandatory treatment to ensure freedom from regulated pests.</p> <p>Q: Who is qualified and authorised to mandate any phytosanitary treatment? Are there any appeal processes against such mandatory treatment?</p>	<p>The application continues: 'This requirement can apply whenever fresh produce are exported to another Australian state, territory or region or to another country that is free of the pest. It also applies to imports into Australia and New Zealand.'</p> <p>For the domestic movement of fruit and vegetables within Australia, this is covered by</p>

Issue and question	FSANZ response
	<p>quarantine controls administered by the relevant enforcement agency in each state and territory. Trade of produce that has been irradiated for a phytosanitary objective is permitted via ICA-55.</p> <p>In terms of overseas imports, all phytosanitary treatments are authorised between the National Plant Protection Organisation (NPPO) in the exporting and importing jurisdictions. For Australia and New Zealand, this is DAWE and Biosecurity New Zealand (in the New Zealand Ministry for Primary Industries (MPI)), respectively. The enforcement functions rest with these quarantine agencies.</p> <p>Horticultural exports are subject to phytosanitary treatments for good reason. Such treatments for regulated pests are an essential part of trade in fresh fruit and vegetables. Countries, states and regions mandate such treatments to ensure that pests that are absent from their territory are not brought in on imported commodities.</p> <p>Establishment of a new pest can threaten the agricultural economy of the importing country or state and have devastating impacts and severe consequences for industries, communities and the environment. Phytosanitary measures therefore play an essential role in protecting the horticultural sectors of both Australia and New Zealand.</p> <p>NPPOs are responsible for conducting pest risk analysis and agreeing on appropriate risk mitigation strategies. Individuals and industry bodies can submit applications to the NPPOs for new or alternative phytosanitary measures as long as they have data sets indicating they are highly efficacious.</p>
<p>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.</p> <p>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'?</p>	<p>See response to Q3 above. Section 2.6 of SD1 provides further technological justification.</p>
<p>25. Only a small fraction is likely to be irradiated.</p> <p>Q: Is this claim justified as the applicant and Steritech clearly intend to promote irradiation as the 'superior' option of choice?</p>	<p>The applicant indicates that to date, the amount of irradiated produce available within Australia has been under 100 tonnes per year. If the application is approved, it is considered likely that it will still only be a small fraction of produce available for domestic consumption that is irradiated. Domestically, this would likely be produce traded between the exporting states Queensland and Victoria (where there is a facility) and the fruit fly free importing states of South Australia, Western Australia and Tasmania. Any produce grown and consumed within the same quarantine region does not need to be irradiated. Existing pre- and post-harvest options for phytosanitary treatments will remain and irradiation will be just</p>

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	<p>one of several phytosanitary options. In some cases, the producers may choose to continue using existing phytosanitary treatments, which are well established within their business, rather than switch to irradiation.</p> <p>Another consideration is supply chain logistics. 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, and it is difficult to fit in to the supply chain for out-of-state produce. See also response to Q22.</p>
<p>26. ... a penetrating treatment ... with no 'dead' spots.</p> <p>Q: Is radiation exposure uniform throughout a treated shipment and is its effectiveness dose dependent?</p>	<p>Radiation exposure is measured by the placement of dosimeters in various places within a shipment. Slight variations in dose of radiation occur within a shipment but exposure to the minimum effective dose is confirmed for all areas.</p>
<p>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.</p> <p>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?</p>	<p>In response to the first question, FSANZ has assessed the application and concluded that the use of phytosanitary irradiation as proposed is technologically justified and effective in achieving its stated purpose. However, DAWE and MPI will also need to undertake import risk analyses, including the assessment of irradiation as an appropriate treatment option, before irradiated produce can be imported into Australia or New Zealand, respectively. These import risk analyses are done independently of the food standards approval process.</p> <p>Various methods exist for detection of irradiated foods. Current detection methods for irradiated food are able to detect whether a food 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.</p> <p>The 'collateral benefits' of treatment e.g. shelf life extension and microbial decontamination are unlikely to be achieved because permitted doses are insufficient for microbial decontamination and they will not markedly increase shelf life.</p>
<p>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).</p> <p>Q: Is this another example of the applicant submitting out of date evidence?</p>	<p>FSANZ conducts its assessment based on the totality of the information provided within the application as well as other available, relevant evidence that FSANZ independently identifies and considers.</p>
<p>29. The mandatory labelling requirements for irradiated produce allows consumers to make informed choices.</p>	<p>See response to Q5.</p>

Issue and question	FSANZ response
<p>Q: Though labels are mandatory, what data shows that the requirement is being monitored and enforced?</p>	
<p>30. We question the applicant's assertions that</p> <ul style="list-style-type: none"> • 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. <p>Qs:</p> <ul style="list-style-type: none"> • 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'? 	<p>FSANZ evaluates the evidence that is provided by the applicant in addition to other relevant information that we identify through our assessment process. FSANZ's nutrition risk assessment conclusions on this application are provided in detail within SD1.</p>
<p>31. FSANZ concluded that</p> <ul style="list-style-type: none"> • Doses no greater than 1 kGy would not adversely affect dietary vitamin C and carotene intakes from all fruit. <p>Q: Where is the published evidence from tests on 'all fruit', to confirm that 'dietary vitamin C and carotene intakes' are not adversely affected?</p>	<p>A comprehensive review of the scientific literature was conducted by FSANZ on the nutritional impact of irradiation on fruit and vegetables. This question is answered in detail in Section 4 of SD1. This included literature that has been published subsequent to the earlier risk assessments and the 2014 review.</p> <p>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 consideration to conclude 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.</p> <p>In addition, 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 fruits and vegetables was based on a representative body of evidence. There is a high proportion of the contribution to vitamin C and β-carotene intakes for commodities that have nutrient impact data (55-85% across Australia and New Zealand for both fruit and vegetables), and there are data for the most</p>

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	commonly consumed commodities (particularly where they contribute highly to nutrient intakes) (see more details in SD1). Therefore, the final conclusion that irradiation of fruit and vegetables will have minimal impact on population nutrient intakes, has been extrapolated to all fruits and vegetables including those where no nutrient impact data are available.
<p>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.</p> <p>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?</p>	<p>In response to the first question, FSANZ's risk assessment is limited to irradiation of that small proportion of fruit and vegetables in the food supply that requires a phytosanitary treatment because this is what the applicant applied for. FSANZ would need to evaluate the public health and safety of any future application that goes beyond the scope of the application.</p> <p>The second question is out of scope. This determination is for other government agencies to make and not FSANZ.</p>
<p>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%).</p> <p>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?</p>	<p>The figure of 0.3% has been calculated by the applicant based on a very conservative estimate that 25% of green and fruiting vegetables presently imported into New Zealand may be switched to an irradiation treatment and that an extra 25% may be imported as a result of new opportunities if the application is approved. In deriving these figures, it is important to bear in mind that New Zealand is virtually self-sufficient in fresh vegetables and little opportunity is seen for irradiated imports.</p> <p>With regards to the second question, even if the application is approved, 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.</p> <p>See also response to Q16.</p>
<p>34. Tables 11 and 12 contain estimates that the irradiation technology owners supplied or commissioned.</p> <p>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?</p>	<p>See response to Q16.</p>
<p>35. Table 13 Assumptions.</p> <p>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?</p>	<p>The assumptions provided in the last column of Table 13 are self-evident (e.g. movement of certain produce interstate requires no phytosanitary treatment) or else based on highly conservative estimates.</p> <p>See also response to Q16 above and Q10 below.</p>
<p>36. The estimates, which are very approximate ...</p> <p>Q: Are they an adequate basis for big decisions, which may have substantial</p>	<p>It is assumed that the submitter's question refers to the estimates for potentially irradiated fresh produce imported into Tasmania (Table 14). FSANZ is unable to comment on fresh food supply's capacity to deliver on health, wellbeing</p>

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<p>impacts on the capacity of the fresh food supply to deliver the health, wellbeing and illness prevention that the public expects?</p>	<p>and illness prevention that the public expects. However, FSANZ can reiterate that it has conducted its own comprehensive nutrition risk assessment and has concluded that any impact of nutrient losses due to irradiation on population nutrient intakes would be minimal.</p>
<p>37. These percentages have been conservatively estimated and could possibly be significantly lower.</p> <p>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?</p>	<p>It is assumed that the submitter's question refers to the percentage of total vitamin intake that could be irradiated for Australians and New Zealanders.</p> <p>FSANZ has conducted its own comprehensive assessment regarding the nutritional impact of phytosanitary irradiation and has determined that any impact of nutrient losses due to irradiation on population nutrient intakes would be minimal.</p> <p>See also response to Q16.</p>
<p>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.</p> <p>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?</p>	<p>The submitter is referring to the following extract from page 43 of the application: 'Recent data on micronutrient changes in fruits, fruiting vegetables and cucurbits are summarised in Appendix 5. <i>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.</i>'</p> <p>The FSANZ 2014 report (FSANZ 2014b) is a peer reviewed report used in the body of evidence for the present application. The data contained in this report is not questionable, rather, it is the result of an evidence based assessment that had regard to FSANZ's statutory criteria, noting that it was prepared and published in anticipation of FSANZ receiving further applications to irradiate various fresh fruit and vegetables in addition to those that were already permitted at that time. The conclusions of the present assessment are generally consistent with those of FSANZ's 2014 report. Subject to any contrary evidence being provided in the interim, these findings stand and remain relevant for this subsequent assessment.</p> <p>FSANZ's risk assessment has been undertaken on the totality of the information provided within the application, the findings presented in the 2014 report, as well as other available, relevant evidence that FSANZ has independently identified and considered.</p>
<p>39. Leafy greens - spinach and fenugreek; lettuce; other. Brassicas – cauliflower; cabbage. Roots and tubers – carrots; sweet potato; potato. Fruit and vegetable juices.</p> <p>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?</p>	<p>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.</p> <p>FSANZ has conducted its own comprehensive assessment of the scientific literature for the current application, that builds upon earlier assessments undertaken as part of multiple previous applications for a range of other commodities. For this application, FSANZ assessed all of the available evidence for leafy vegetables, roots and tubers and Brassicas as outlined in Appendix 5 of SD1.</p>

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	<p>In addition, FSANZ estimated the nutrient contribution from the commodities with available nutrient impact data compared to the contribution from all fruit 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.</p> <p>There is a high proportion of the contribution to vitamin C and β-carotene intakes for commodities that have nutrient impact data (55-85% across Australia and New Zealand for both fruit and vegetables), and there are data for the most commonly consumed commodities (particularly where they contribute highly to nutrient intakes) (see more details in the SD1). Therefore, the final conclusion that irradiation of fruits and vegetables will have minimal impact on population nutrient intakes, can be extrapolated to be relevant for all fruits and vegetables including those where no nutrient impact data are available.</p>
<p>40. We conclude that the risk of an adverse nutritional impact from approving phytosanitary irradiation for all fresh produce is of no practical concern.</p> <p>Q: What level of 'adverse nutritional impact' would be of 'practical concern'?</p>	<p>FSANZ cannot comment on the applicant's understanding/definition of what level of adverse nutritional impact would be of practical concern.</p> <p>As part of a detailed dietary intake assessment, FSANZ would evaluate if irradiation would result in reductions in population nutrient intakes that would cause the proportion of the population with inadequate intakes (i.e. the percent less than the Estimated Average Requirement (EAR)) to increase significantly indicating a potential cause for concern. Irrespective of the conclusions reached by the applicant, FSANZ has conducted its own comprehensive nutrition risk assessment and has concluded that any impact of nutrient losses due to irradiation on population nutrient intakes would be minimal.</p>
<p>41. 3.2. Toxicological data</p> <p>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?</p>	<p>FSANZ's risk assessment has been undertaken on the totality of the information provided within the application as well as recent literature on the topic FSANZ has independently searched and located. The safety of irradiated food is not an area in which there is much active research, because it is considered to be well established.</p>
<p>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.</p> <p>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'?</p> <p>What authorities 'generally considered' that furans would not be high enough to have a toxicological effect?</p>	<p>The issue of furan has been addressed in Section 3.2.2.1 of SD1. FSANZ's assessment of the risk of furan is based on publications located in the peer-reviewed scientific literature by FSANZ, not on the statements in the application. The literature reviewed supports the assertion by the applicant that furan is likely to be at undetectable levels, see the paper by Fan and Sokorai (2008). Their findings are summarised in SD1.</p> <p>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. In addition, consideration of the potential worst case dietary exposure to furan from irradiated fruit and vegetables was estimated (based on maximum determined residues of furan after irradiation at 5 kGy) and a comparison made with total dietary</p>

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	exposure to furan. This showed that furan from irradiated fruit and vegetables is likely to be negligible in the context of total dietary exposure.
<p>43. Possible furan production does not appear to be a realistic risk following phytosanitary irradiation (EFSA 2011a).</p> <p>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”?</p>	<p>The EFSA Scientific Opinion is based on a thorough review of the peer-reviewed scientific literature, and is fully referenced.</p> <p>Genotoxicity assays are most commonly <i>in vitro</i> rather than <i>in vivo</i>. The standard genotoxicity battery of assays includes the bacterial reverse mutation assay (Ames test), the chromosomal aberration assay, and the micronucleus assay. The first two of these are <i>in vitro</i> assays, and the micronucleus assay may be <i>in vivo</i> or <i>in vitro</i>.</p> <p>FSANZ does not base its safety assessment on applicants’ assertions, or on the assertions of EFSA, but conducts its own literature reviews and risk assessment, as described in SD1.</p>
<p>44. Pet food</p> <p>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?</p>	<p>At the time that the irradiated Origen cat food was imported, similarly irradiated Origen dog food was also imported. Some of the cats that became ill consumed Origen dog food rather than Origen cat food. The irradiated Origen dog food did not cause neurological illness in any dogs.</p> <p>Irradiated animal chow is widely used in animal research laboratories and there are a number of commercial suppliers of such diets. Some animals, such as rodent models of severe combined immunodeficiency, have been fed entirely on irradiated animal chow for many generations, with no adverse effects. On the other hand, the neurological problems in Australian domestic cats fed irradiated cat food have been replicated in some laboratory cat colonies.</p> <p>Some people have been on entirely irradiated diets for protracted periods, e.g. astronauts, and patients with severe immunodeficiencies (acquired or congenital). No neurological disorders comparable to those observed in the cats fed the irradiated Origen cat food have been observed in any of those people.</p>
<p>45. 3.4. Microbiological data Not relevant to the request for a phytosanitary purpose.</p> <p>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?</p>	<p>The applicant has not ignored these consequences of irradiation, rather, these are not relevant because the permitted doses are insufficient for microbial decontamination and they will not markedly increase shelf life.</p> <p>See also response to Q27.</p>
<p>46. AS2070 –1999 ... includes such items as packages, domestic containers, wrapping materials, utensils or any other plastics items intended for food contact applications (SA1999).</p> <p>Q: As this Standard predates the commercial irradiation of foods, does it provide</p>	<p>The Code stipulates 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</p>

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<p>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?</p>	<p>intended to be irradiated. Leaching that results in contamination of food would be an enforcement issue.</p> <p>Also note that Standards Australia is an independent standard settings body unrelated to FSANZ. Standards set by Standards Australia (such as AS2070-1999) are not mandatory and are generally considered to be guidance information.</p>
<p>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“.</p> <p>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”?</p>	<p>It is assumed that the submitter is referring to section 10.2 of the Conclusions on the acceptability of irradiated food in the report Wholesomeness of irradiated food (JECFI 1981).</p> <p>The section reads in full “The Committee considered that the irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems. However, the Committee emphasized 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”. The rest of the submitter’s statement is not part of this quote, although they have put in quotation marks.</p> <p>FSANZ has conducted a comprehensive nutrition risk assessment and has concluded that any impact of nutrient losses due to irradiation (at the permitted levels) on population nutrient intakes would be minimal. Where the nutrition risk assessment indicated there was a loss in nutrient content in specific commodities due to irradiation, the contribution those commodities made to total dietary intakes for the relevant nutrient were investigated. The results of this investigation (as outlined in Section 5.2 in SD1) showed that those commodities only contributed a small proportion to total nutrient intakes.</p> <p>The permitted doses are insufficient for microbiological decontamination.</p>
<p>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.</p> <p>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?</p>	<p>The Queensland DPI policy is always to use Good Agricultural Practice (GAP) and this is consistent with the Commonwealth’s Australian Pesticides and Veterinary Medicine Authority (APVMA) policy on setting of maximum residue limits for agricultural and veterinary chemicals. If pre-harvest fruit fly control measures are not in place the amount of damage caused by fruit fly larvae can result in fruit being unmarketable. No treatment (irradiation, fumigation etc.) will improve the quality of the fruit if infestation levels are left unchecked.</p> <p>Irradiation is an alternative treatment to post-harvest insecticide treatment which is permitted for a range of commodities.</p>
<p>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.</p> <p>Q: Is helping shoppers to make informed decisions about their food purchases</p>	<p>We do not expect consumer choice to be significantly impacted by A1193, as only a small proportion of fruit and vegetables are likely to be irradiated.</p>

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<p>more important than having choice, as A1193 could reduce or eliminate the choice of buying un-irradiated fruits and vegetables?</p>	
<p>50. 5.2. Consumer acceptance</p> <p>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?</p>	<p>FSANZ notes these are references cited by the applicant. As part of the response to Recommendation 34 of the Labelling Review, FSANZ undertook a comprehensive assessment of available consumer literature (see response to Q22).</p> <p>In addition, the 2015 FSANZ Consumer Label Survey reported between 10-15% of Australian and New Zealand consumers aged 15 and over usually look for irradiation information when purchasing a food for the first time (FSANZ 2017 https://www.foodstandards.gov.au/publications/Pages/consumerlabelsurvey2015.aspx).</p> <p>The application does not seek to permit the irradiation of all fruits and vegetables in the food supply, rather it provides a safe post-harvest phytosanitary treatment option for industry to use on that small proportion of all fruit and vegetables that are to be transported into another quarantine region.</p>
<p>51. Commodity tolerance</p> <p>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.</p> <p>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?</p>	<p>To clarify, whilst the application does seek approval to irradiate all fresh fruit and vegetables, any permission would cover a phytosanitary objective only. Excluded from scope are legumes (and dried pulses).</p> <p>With regards to commodity tolerance, the applicant states that as experience is gained with optimising irradiation and supply chain logistics for fresh produce, it is becoming clear that more fruit and vegetables can tolerate phytosanitary doses than was thought likely a few years ago. An example is citrus fruits, which were thought to be intolerant of irradiation. However, more recently, many citrus varieties have been shown to withstand phytosanitary doses.</p> <p>Given the probability that more crops will be found suitable for irradiation as experience is gained with phytosanitary irradiation, the application does not 'cherry-pick' certain crops to be added to the existing permissions in Standard 1.5.3. Rather, the application seeks a generic permission, noting that, in the event of a foreign or exotic pest incursion, irradiation may be sought out as a viable treatment for many vegetable and fruit crops. The inability to use irradiation as a generic treatment in such situations places the entire Australian horticultural industry at unnecessary risk.</p> <p>Possible exceptions include produce that auto-oxidises quickly, such as avocado, which has a low tolerance to irradiation, with detrimental effects like discolouration occurring. Irradiation is not likely to be used commercially for this product.</p> <p>Even though the permission being sought is for all fruit and vegetables, there will be no benefit to using irradiation on any products (such as avocado) that cannot tolerate</p>

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	<p>phytosanitary doses.</p> <p>Tables 1 and 2 of Appendix 3 of the application outline the potential for phytosanitary irradiation treatment for various produce items in the medium term, based on commercial significance and supply and demand influences.</p>
<p>52. Table: Recent data on effects of radiation on leafy greens, brassicas and roots and tubers</p> <p>Q: Should the results of those studies that irradiated samples at doses far outside the proposed range of approved doses be discarded?</p>	<p>Application A1193 requests permission for the use of phytosanitary doses of irradiation in the range of 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 evidence. The effects of irradiation on 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.</p>
<p>53. Significant – how important?</p> <p>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?</p>	<p>In FSANZ safety assessments, the word ‘significant’ is only used when there is statistical significance. The use of the word in an application will not be carried across to a safety assessment without statistical significance being shown in a report in the peer-reviewed scientific literature.</p> <p>Regardless of the more general use of the word in the application, the word ‘significant’ has not been used in SD1 other than in the context described above. The word ‘significance’ is also used only in the context of statistical significance, with the sole exception of one reference to ‘insects of quarantine significance’ where the alternate meaning of the word is clear.</p>
<p>Questions from Food Irradiation Watch/Gene Ethics regarding SD1</p>	
<p>1. A1193 permission would apply to both domestically produced and imported fruit and vegetables requiring a phytosanitary treatment.</p> <p>Q: What are the objective criteria and procedure for a decision that treatment is required or not required?</p>	<p>FSANZ cannot comment on this issue other than to say that the relevant biosecurity agencies in each jurisdiction would be responsible for determining whether a phytosanitary treatment is/is not required in order to move certain products from one quarantine region into another. If this application is approved, irradiation would be one of a number of existing treatment options that may fulfil this requirement.</p>
<p>2. Irradiation as a phytosanitary measure is not a substitute for good hygienic, manufacturing or agricultural practices.</p> <p>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?</p>	<p>See response to Q7 above.</p>
<p>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.</p>	<p>See responses to Q41 and Q52.</p> <p>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. This included</p>

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<p>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.</p>	<p>literature that has been published subsequent to the earlier risk assessments and the 2014 review.</p> <p>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 fruits and vegetables was based on a representative body of evidence. There is a high proportion of the contribution to vitamin C and β-carotene intakes for commodities that have nutrient impact data (55-85% across Australia and New Zealand for both fruit and vegetables), and there are data for the most commonly consumed commodities (particularly where they contribute highly to nutrient intakes) (see more details in SD1). Therefore, the final conclusion that irradiation of fruit and vegetables will have minimal impact on population nutrient intakes, has been extrapolated to all fruit and vegetables including those where no nutrient impact data are available.</p>
<p>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.</p> <p>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?</p>	<p>The literature searches on which this statement is based are described in SD1.</p>
<p>5. FSANZ 'decided that the minor nutrient losses caused by irradiation were not a concern for public health.'</p> <p>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?</p>	<p>The submitter is referring to a sentence in the Executive Summary of SD1, which reads in full "FSANZ previously reviewed the nutritional impact of phytosanitary irradiation on 22 fruits and four vegetables (Applications A0443, A1038, A1069, A1092, and A1115) as well as on herbs and spices (Application A0413) and decided that the minor nutrient losses caused by irradiation were not a concern for public health."</p> <p>FSANZ's risk assessments for these applications are available on the FSANZ website or else upon request. The 2014 FSANZ report Nutritional impact of phytosanitary irradiation of fruits and vegetables also provided evidence in support of FSANZ's conclusions for this latest application. Three categories of vegetables, namely Brassicas, roots and tubers and leafy vegetables that were not previously reviewed by FSANZ were assessed in A1193, see Section 4 of SD1.</p> <p>As stated for Q49, there is no evidence to indicate that the approval of A1193 will result in a great increase in the scope and scale of irradiation. The dietary intake assessment is outlined in Section 5 of SD1. The dietary intake data included in the assessment are for the whole population which includes population sub-groups.</p>

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<p>6. Vitamin A (retinol) which is highly sensitive to irradiation was excluded from the nutritional assessment because retinol is not present in plant foods.</p> <p>Q: Why has FSANZ not fact-checked this false statement?</p>	<p>Vitamin A exists as two forms in food, pre-formed retinol and the precursor to vitamin A – carotenes including beta 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 (beta carotene), which can be converted to retinol in the body is found in some fruits and vegetables and has medium sensitivity to irradiation (see Figure 1 of SD1). Please refer to the following link for further information: https://www.nrv.gov.au/nutrients/vitamin-a</p>
<p>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.</p> <p>Q: Why is the applicant not required to provide adequate evidence?</p>	<p>See response to Q18.</p>
<p>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%).</p> <p>Q: To which population does this claim refer? What is the status of thiamin and vitamin E in fresh fruit?</p>	<p>This refers to the whole Australian and New Zealand populations. Contributions across the range of age/sex groups were evaluated and this conclusion applies across the populations.</p>
<p>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.</p> <p>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’?</p>	<p>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 beta-carotene. FSANZ made this decision on the basis of previous expert opinions by the World Health Organization 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. Thiamin and vitamin E are also considered sensitive to irradiation; however, fruit and vegetables account for only a small proportion of these two nutrients in the Australian and New Zealand diet.</p>
<p>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.</p> <p>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.</p>	<p>FSANZ is of the view that this statement does accord with industry’s future projections, taking into account the restricted scope and voluntary nature of the proposed permission, the suitability of irradiation for every situation, and the availability of other existing treatments.</p> <p>Specifically, the applicant indicated that if the application is approved, the potential availability of irradiated produce in New Zealand would amount to 0.3% of vegetables and 8% of total fruits. For Australia, it would amount to only 3% of total fruit and 1.2% of total vegetables (imported from other countries or cross border importation). This is a conservative estimate meaning it is the greatest proportion of irradiated fruit and vegetables that may be consumed. No evidence to the contrary was provided by submitters (including</p>

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	<p>the relevant biosecurity agencies) or located by FSANZ.</p> <p>See also response to no. 16 regarding the estimates provided by the applicant.</p> <p>A statutory mechanism exists by which permissions in the Code can be formally reviewed and amended by FSANZ should credible new information arise suggesting that a food standard may no longer be appropriate. This could be in relation to public health and safety, labelling or enforcement concerns. FSANZ has a strong track record of reviewing existing standards in this manner. It is not possible to pre-empt the likelihood or timing of any future reassessment of irradiated food only to state that it can be undertaken if necessary.</p>
<p>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.</p> <p>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?</p>	<p>FSANZ maintains a watching brief on peer-reviewed scientific literature that may affect regulatory decisions made by FSANZ or by JECFA.</p> <p>FSANZ is required to publish information about progress on applications under the FSANZ Act 1991 and does this through its Notification Circulars, Gazette notices and Work Plan, which are publically available on the FSANZ website.</p> <p>Subsequent to gazettal, reporting relating to compliance and enforcement is undertaken by the relevant Australian and New Zealand enforcement agencies. FSANZ does not have the legal authority to enforce the Code.</p>