APPLICATION TO FSANZ

Application to amend Standard 1.5.3 of the Food Standards Code, Irradiation of Food, to include irradiation as a phytosanitary measure for all fresh fruits and vegetables.

EXECUTIVE SUMMARY

Date Submitted: *06/11/2019*

This application seeks a variation to the Food Standards Code, Standard 1.5.3 Irradiation of Food (FSANZ 2017). The variation requested is to replace the list of 26 fruits and vegetables in the table in Division 2, section 1.5.3-3, sub-section 2, with “fresh fruits and vegetables”. Included in the scope of the application are all those fresh fruits and vegetables presently described within Schedule 22 of the Food Standards Code plus any other fresh commodity generally understood to be a fruit or vegetable, including crops grown overseas. Excluded from the application are dried pulses, legumes, nuts and seeds.

Under the proposed amendment the purpose of the irradiation of fruits and vegetables and the minimum and maximum absorbed doses will remain the same **(**Division 2, section 1.5.3-3, sub-section **1).** That is, the purpose is pest disinfestation for a phytosanitary objective and the minimum and maximum absorbed doses are 150 Gy and 1 kGy, respectively.

Applicant

This application is submitted by the Queensland Department of Agriculture and Fisheries (QLD DAF). QLD DAF's focus is on areas of policy development, leading-edge science, biosecurity, fisheries and forestry management, trade and export. The Agriculture Business Group focuses on lifting the productivity of Queensland’s food and fibre businesses.

Purpose

The purpose of the amendment is to extend the option of phytosanitary irradiation to all types of fresh fruits and vegetables. The existing Standard 1.5.3 approves irradiation for a phytosanitary purpose for 26 fruits or vegetables.

A phytosanitary measure is required whenever commodities are subject to a mandatory treatment to ensure freedom from regulated pests. This requirement can apply whenever fresh produce is exported to another Australian state, territory or region or to another country that is free of the pest. The requirement also applies to imports into Australia and New Zealand. Irradiation at doses between 150 Gy and 1 kGy is a highly effective phytosanitary measure. It is well suited to assist in expanding market access, both export and import, and for the evolving regulatory and international trade environment for fresh produce.

Justification

Phytosanitary measures for imports are used to protect the horticultural sectors of both Australia and New Zealand that have a value of several billion dollars. Similarly, horticultural exports from Australia and New Zealand may be subject to pre-shipment phytosanitary treatments. The majority of the fresh produce consumed in both countries is not subject to a treatment as it is produced and eaten in the same quarantine jurisdiction.

There is a range of treatments that may be used as phytosanitary measures. The options can be 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. Irradiation is the most recently established option. Each has different advantages and disadvantages. The key advantages of irradiation are that –

- It is subject to internationally recognized protocols (FAO IPPC 2003) and is unique among phytosanitary treatments as a broad-spectrum treatment for almost all important regulated arthropod pests (Follett and Neven 2006). A minimum dose of 150 Gy is internationally recognized as a generic treatment for all Tephritid fruit flies in all host fruits and vegetables (FAO IPPC 2009c). Australian states and territories and the USA recognise 400 Gy as a generic treatment of all insects in all host fruits and vegetables except adult *Lepidoptera* that pupate internally (USDA 2006; ICA 2011).
- Unlike competing treatments, long and costly research on host produce that have not been previously investigated is no longer required to prove effectiveness against fruit flies and most insects.
- It is a chemical-free treatment resulting in no harmful treatment residues on the produce and no release of any chemicals that may be harmful to the environment, including the ozone layer, or human health.
- It has the practical advantages of simplicity, application at the optimum storage temperature of the produce and independence from ambient conditions such as temperature, humidity and pressure. It is a rapid, well-tolerated treatment that is penetrating and applied to the commodity in its final packaging.

The first FSANZ approval of phytosanitary irradiation was for nine tropical fruits in 2004. Further approvals followed for 17 more fruits and fruiting vegetables (2011 to 2016), Australian exports of irradiated fresh produce have grown from 19 tonnes of mangoes exported to New Zealand in 2004 to over 5,300 tonnes of 10 different fruits and vegetables to 5 countries.

Five countries have negotiated access to Australia for irradiated fruits. Vietnam (mango, litchi) and India (mango) have begun exporting irradiated fruit to Australia.

Modification of Standard 1.5.3 as requested would further increase both market access opportunities for Australian exports and the availability of imported fresh produce to the benefit of the health and choice of Australian and New Zealand consumers.

International phytosanitary practice in traded fresh produce has evolved during the last decade. The initial trans-Tasman trade in irradiated mango in 2004 was the first truly international trade in irradiated fresh produce. Since then phytosanitary irradiation has become firmly established as a phytosanitary measure of choice between many trading partners (Roberts and Follett 2018). There are now at least 15 countries trading in irradiated produce (USDA 2018 and Table 1). Over 40,000 tonnes of irradiated fresh produce is now being traded internationally.

Approval of phytosanitary irradiation for all fresh produce would make Standard 1.5.3 fit-for-purpose in today's trading environment for several reasons.

Choice of most appropriate treatment

In Australia and New Zealand, irradiation is the only phytosanitary treatment that requires a variation to a food standard before it can be considered by biosecurity authorities. This is a barrier to uptake by the horticulture industry as a result of the time and cost involved and the perception that irradiation must be uniquely hazardous and difficult. Approval of this application would ensure that industries choose a phytosanitary treatment governed solely by which option is optimal, based on effectiveness, quality retention and cost.

Reducing environmental and health hazards

Fumigation using methyl bromide (MeBr) is a frequently used phytosanitary measure but it is a known ozone depleting gas (UNEP 2019) and replacement by irradiation is regarded as a good option for encouraging the reduction and replacement of MeBr fumigation (UNEP 2016). MeBr is also a known human health and workplace hazard (USEPA 2019, MPI 2019). The use of insecticides is being increasingly restricted and irradiation provides a replacement option.

Harmonisation of regulations and reciprocal trade arrangements

With the exception of Australia and New Zealand, all the countries that are presently trading in irradiated fruits and vegetables approve phytosanitary irradiation for all fruits and vegetables. Many other countries, some of which are likely target markets for irradiated Australian exports, also approve irradiation treatment of all fresh fruits and vegetables (GHI 2018; PNS 2015; FDA 2019; DOH 2018; EU 2009a).

While Australia is expanding exports of irradiated fruit to several Asian countries and the USA, some economically important fruits grown in such countries cannot be irradiated and imported into Australia as they are not already FSANZ approved. As they are not grown significantly in Australia, local industry is unlikely to lodge an amendment application. Overseas markets can question why Australian industry seeks to export produce to their country when that product is not approved (i.e., considered safe) within Australia. Access to a market can be expedited if the importing country knows that a reciprocal approval for its commodities is possible.

A generic approval for phytosanitary irradiation would bring Standard 1.5.3 fully into line with international standards and recommendations. The Codex General Standard (CAC 2003a) treats irradiation as any other food process that is safe and nutritionally adequate for any food. The WHO Sanitary and Phytosanitary Agreement requires all measures to be the least restrictive to trade (WTO 2011).

The International Plant Protection Convention is the recognised agency for establishing global practice in phytosanitary measures (IPPC 2019a) through its International Standards for Phytosanitary Measures (IPPC 2019b) or ISPMs. Harmonisation of phytosanitary irradiation treatments for regulated pests through ISPM 18 and ISPM 28 (FAO IPPC 2003, 2007) support efficient and effective phytosanitary measures and encourage the mutual recognition of treatment efficacy and treatment delivery. This can facilitate domestic and international trade. ISPM 28 Appendix 7 recognises 150 Gy as the dose to guarantee sterility, preventing adult emergence, of all fruit flies in all hosts (FAO IPPC 2009c). These measures apply to all fresh fruits and vegetables and Australian states have agreed to take the same approach via ICA 55 (ICA 2011). 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*. It is already recognised as such by the USA and by Australian states and territories (USDA 2006, ICA 2011).

Other considerations

A generic approval for phytosanitary irradiation will allow a rapid response to new opportunities, threats and emergency requirements. As experience is gained with optimising irradiation and supply chain logistics for fresh produce it is becoming clear that more fruits and vegetables can tolerate phytosanitary doses than was thought likely a few years ago. For example, some citrus types are now traded overseas. As a treatment that requires no research on most pest-host combinations, irradiation is ideally placed to ensure that markets are not lost when existing treatments are no longer viable or approved, as was the case with tomatoes to New Zealand a few years ago. Irradiation can also be put in place rapidly for niche opportunities in the marketplace and can be used as an emergency measure when a pest incursion is suspected.

Costs and benefits

The socio-economic value of Australian and New Zealand horticulture industries (production, export, supply chain and retail) to both central and state governments is substantial. Phytosanitary measures such as irradiation help protect and expand these industries. There is significant benefit in having a range of phytosanitary measures available especially as chemical treatments and fumigation come under greater scrutiny and restrictions.

There are costs to providing irradiation treatments including not only the processing costs but transport to a specialised facility, packaging and labelling. 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. The present average costs of treatment at the Steritech facility of $170 per tonne or $0.17c per kg (private communication) will not add significantly to the cost of high value fruits and vegetables.

The acceptance of irradiation as a phytosanitary treatment option may speed up and reduce the costs of negotiations for market access of some Australian exports. Research into effectiveness against fruit flies is no longer required for irradiation, unlike other treatments. The loss of export markets is costly to industry and it is often challenging and complex to re-enter markets, as export markets are very competitive. Addition of irradiation to the treatment options available will mitigate against the changes that can occur, sometimes very rapidly, in the importing requirements of Australia’s trading partners.

Industry benefits when the best possible choice from various treatment options can be made. If irradiation is approved as a generic treatment, then choice will be based solely on effectiveness, quality retention and cost. This will allow the optimum choice to be made, for example, when comparing cold storage *versus* irradiation treatments, sea-freight *versus* air freight.

A simplified (i.e., generic) approval of phytosanitary irradiation will also be beneficial to both government and industry through a reduction in regulatory and management costs.

Cost considerations regarding capital investment, an inability to feasibly locate a treatment facility within packing facilities, and remaining concerns about the process by key decision makers, packers, shippers, and retailers remain challenges.

The estimates for the percentage of fresh fruits and vegetables that may be irradiated if phytosanitary irradiation is permitted for all fresh produce (see below) suggest that the effect on the overall volumes and types of fresh produce consumed will not be large. This is because the majority of fresh produce is consumed within the production region and not subject to a phytosanitary treatment, and alternative treatment methods will still be available. There will be a benefit from new fruits from overseas that are not presently available entering the local markets.

A generic approval will not mean the unjustified use of irradiation. Standard 1.5.3 requires irradiation of fruits and vegetables to be for a phytosanitary purpose. For commodities being sold in markets with no phytosanitary restrictions, the use of irradiation would not be required or permitted. All phytosanitary treatments are authorised under established protocols between national or state plant protection agencies. The full range of traditional phytosanitary measures will still be available and will often remain the best option.

Safety and dietary impact

There has been no revision of international scientific opinion or significant literature on the toxicological or microbiological effects of irradiation on food since the most recent Applications to amend Standard 1.5.3.

Macronutrients are not significantly affected at low doses and minerals and trace elements are not sensitive to irradiation. Vitamins, however, range from relatively high to low sensitivity to radiation with vitamin C, thiamine, vitamin E and Vitamin A being most sensitive.

A 2014 review by FSANZ (2014b) concluded that phytosanitary doses of irradiation:

- Have no effect on carotene levels in fruits and vegetables;
- Have little effect on non-vitamin bioactives;
- Do not decrease vitamin C levels in the majority of fruits and vegetables;
- For fruits and vegetables where a decrease in vitamin C is reported, the decrease is no greater than for other processing methods. Most importantly, vitamin C levels remain well within the range of concentrations that can result from natural variations, storage and processing.

On the basis of the available data and dietary modelling, FSANZ also concluded that

- Doses no greater than 1 kGy would not adversely affect dietary vitamin C and carotene intakes from all fruit.
- 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.

This application presents further data from more recent literature, including data for several vegetables. It also presents data from another review of irradiation -induced changes to sensitive micronutrients (Barkai-Golan and Follett 2017); and from literature on leafy vegetables, potatoes and citrus. Overall the literature indicates that no significant micronutrient losses, specifically vitamin C, are observed from individual fruits or vegetables treated with phytosanitary irradiation. Similar conclusions and a consequent finding that there would be no significant impact on the intake of dietary nutrients have been a basis for the previous approvals of individual or groups of fresh produce.

This application, however, requests approval for phytosanitary irradiation of all fresh produce and the issue of any potential impact on dietary nutrient intake should be assessed more fully. This has been done by assuming that irradiation is fully available as one of several potential phytosanitary measures along with cold, heat, fumigation and area-free systems.

The first steps taken to estimate the potential impact on dietary nutrient intake for Australia and New Zealand were to estimate:

- Total consumption (tonnes) of fresh fruits and vegetables sub-divided into major categories (Prowse 2019).
- The tonnes and percentage of total consumption that involved produce imported across a border and, therefore, potentially subject to a phytosanitary measure; the border could be national (for overseas imports) or, for Australia, an inter-state boundary (Prowse 2019).
- 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) and used to calculate the percentage of total consumption that might be irradiated.

With these conservative estimates, it was calculated that, for New Zealand, 8% of total fruit and 0.3% of total vegetables consumed might be irradiated in future. For Australia, 3% and 1.2% of total fruit and vegetables consumed might be irradiated. However, consumption of imported fruits and vegetables is not the same across all Australian states, with Tasmania especially importing significantly above average amounts. As a worst-case scenario, it was estimated that for Tasmanians irradiated imports might be 15% and 6% of total fresh fruit and vegetables respectively.

New Zealand consumers (aged 15+) obtain 22.4% and 28.1% of their vitamin C from fresh fruits and fresh vegetables (excluding potatoes, kumara and taro) respectively (MOH 2003, 2011). Therefore, approximately 1.8% plus 0.1% (1.9%) of total vitamin C intake could be irradiated. Australian consumers (aged 2+) obtain 25.8% and 26.8% of their vitamin C from fresh fruits and fresh vegetables respectively (ABS 2014a). Therefore, approximately 0.8% plus 0.3% (1.1%) of total vitamin C intake could be irradiated. For Tasmania, as a worst-case scenario, 3.9% and 1.6% (5.5%) of total vitamin C intake could be irradiated.

Australians and New Zealanders generally have a nutritionally adequate diet (FSANZ 2014b). Even in people with the lowest intake levels, vitamin C intake is adequate. It is also pertinent that the vitamin C content of even the same fruit or vegetable variety is subject to natural, storage and processing variations significantly greater than any radiation -induced change.

For the worst-case scenario of Tasmania, a 1% drop of in total vitamin C intake would require all the fruits and vegetables with potential to be irradiated to be treated with phytosanitary doses and for such doses to cause an approximate 15-20% decrease in vitamin C activity. For Australia and New Zealand nationally, the decrease caused would have to be about 90% and 50% respectively. Phytosanitary doses are usually in the range 420 to 840 Gy. The literature indicates that the average decrease is far more likely to be zero, very small or even a slight increase if total anti-oxidant activity is measured.

In summary, the present micronutrient status of Australian and New Zealand consumers is more than sufficient and any loss of vitamins through phytosanitary irradiation will be negligible and much less than other variations. We conclude that the risk of an adverse nutritional impact from approving phytosanitary irradiation for all fresh produce is of no practical concern.

Regulatory and legislative impacts

The internationally recognized standard-setting agencies for human and plant health are Codex Alimentarius and the International Plant Protection Commission (IPPC). The international regulatory and legislative standards and criteria related to irradiated food and phytosanitary measures have not changed recently (CAC 2003a,b; FAO IPPC 2003, 2007, 2009a,b,c).

National regulations on food irradiation have also remained largely unchanged with almost 60 countries approving irradiation of at least one food and application. However, far fewer are actually using food irradiation commercially (Roberts 2016). Of more interest to this Application is the significant number of countries that approve phytosanitary irradiation for all fruits and vegetables. This includes all the countries other than Australia and New Zealand trading in irradiated fresh produce, several other countries that could be future markets for irradiated Australian produce and several countries in South America and the EU.

Other implications

Environment

Greater use of irradiation as a phytosanitary measure will provide an alternative to MeBr fumigation which has detrimental effects on the ozone layer (UNEP 2019) and potentially on human health (USEPA 2019, MPI 2019). Irradiation is already reducing MeBr use for produce entering the USA. It has the potential to reduce MeBr use more widely (FAO IPPC 2008; UNEP 2016) and also to reduce use of post-harvest insecticides. In-depth environmental assessments of phytosanitary irradiation in the USA found irradiation would not have a significant impact on the quality of the human environment (USDA 1997, 2002).

There are strict guidelines and standards on the establishment and routine operation of irradiation facilities and on the transport and disposal of radioactive material. A second food irradiation facility being constructed in Melbourne is an X-ray facility that neither uses nor produces radioactive material. This is an example of a trend towards use of non-radioactive radiation sources.

The purpose of phytosanitary measures is to prevent the spread of plant pests which could have devastating impacts and severe consequences for industries, communities and the environment.

Consumers

Numerous surveys of consumer acceptance of irradiation have generally indicated consumer opposition or reluctance to purchase irradiated foods, including a 2002 study of New Zealand and Australia consumers (Gamble 2002). Some of the studies, including the local study, suggest that consumers may be more concerned about chemical residues than irradiation. However, most surveys were conducted in situations when irradiated produce was not available for sale and there was no option to fully evaluate or purchase irradiated product. However, there is now significant experience of consumers having the option to purchase irradiated food. A review of actual purchase behaviour suggests that while a fraction of the public will not buy irradiated food, a much larger fraction will (Roberts and Henon 2015).

There has been no negative reaction to 15 years of irradiated mango sales in New Zealand. Retail sales of irradiated tomatoes have been far smaller but, apart from some negative comments from the domestic tomato industry and some members of the public prior to the commencement of such trade, there has been no adverse reaction since. 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.

There is educational material to help consumers make better-informed choices regarding irradiated fruit and vegetables. The mandatory labelling of irradiated fruit and vegetables provides consumers with choice when it comes to purchasing or not purchasing irradiated fruit and vegetables.