

Attachment D

COAG Decision Regulation Impact Statement – Proposal P1016

Hydrocyanic Acid in Apricot Kernels & Other Foods



Raw skin on (unhulled) apricot kernels



Raw skin off (hulled) apricot kernels

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Executive summary

This Decision Regulation Impact Statement (Decision RIS) has been prepared for Proposal P1016 – Hydrocyanic Acid in Apricot Kernels and Other Foods. The Decision RIS examines the options available to address the public health and safety problems identified with the retail sale of raw apricot kernels in Australia and New Zealand.

Along with other foods, apricot kernels contain cyanogenic glycosides which may pose a health risk to consumers. The toxicity of cyanogenic glycosides in humans and animals arises because it is converted by gut bacteria to hydrocyanic acid (HCN). If sufficient cyanogenic glycosides are consumed, then cyanide poisoning may follow.

The concentration of cyanogenic glycosides (but reported as HCN equivalents) in raw apricot kernels on the market varies considerably, possibly due to environmental factors during cultivation or the processing procedures applied following harvest. Published and unpublished data indicates that these kernels contain sufficient HCN (equivalents) to cause cyanide poisoning if ingested. For example, in 2010-13, the Implementation Sub-Committee for Food Regulation's unpublished survey of skin-on kernels showed a range of 1,240 to 2,820 mg/kg of HCN, compared to skin-off kernels at 49 to 440 mg/kg. Added to these large variations in HCN levels is the increased marketing and promotion of raw apricot kernels as a health food, or as a possible 'miracle cure' for cancer.

The purpose of the following analysis is to determine whether measures can be put in place to manage potential public health and safety issues from consumption of raw apricot kernels in a way that addresses the risk for consumers, yet is mindful of industry impacts.

Food Standards Australia New Zealand (FSANZ) made considerable efforts to consult with key stakeholders; including the receipt of formal submissions in response to the Call for Submissions and the Consultation RIS, as well as direct consultation with industry and state and territory enforcement agencies. However, difficulties were experienced in obtaining sufficient information for detailed quantitative analysis of the proposed options. Therefore, this Decision RIS is largely qualitative in nature.

A Consultation RIS (OBPR Reference 16574), consistent with the Council of Australian Government's (COAG) best practice regulation requirements, was released for consultation from 16 December 2014 to 10 February 2015 with a Call for Submissions. Five options were presented:

- Option 1: Maintain the status quo
- Option 2: Mandatory labelling of all raw apricot kernels
- Option 3: Set a maximum level of HCN for raw apricot kernels
- Option 4: Prohibition on the retail sale of raw skin on apricot kernels – in parallel, require manufacturers to provide advice for consumers on the maximum amount of skin off apricot kernels that could safely be consumed on their labels.
- Option 5: Prohibition on the retail sale of all raw apricot kernels – prohibition covers both skin on and skin off kernels.

All options exempt foods containing raw apricot kernels as an ingredient (such as amaretti biscuits) where they have been subject to a treatment or processing step that renders them safe for human consumption. The prohibition would not apply to fresh whole apricots which contain raw apricot kernels.

The risk assessment undertaken by FSANZ indicates that consumption of skin-on raw apricot kernels poses an acute public health and safety risk for consumers due to the risk of cyanide poisoning from the release of hydrocyanic acid, which can lead to death. Sub-lethal doses have been reported as causing abdominal pain, headache, dizziness, palpitations and other symptoms.

Cyanide poisoning incidents following consumption of raw apricot kernels have been confirmed in Australia, New Zealand, Hong Kong, Canada, USA, United Kingdom and other European countries. Data on poisoning incidents from Australian and New Zealand poisons information centres reveal that there have been a number of calls to these centres following either accidental (children and adults) or intentional ingestion (by adults only) of raw apricot kernels.

Raw apricot kernels are available to consumers in Australia and New Zealand through retail outlets (including health food stores) and websites. These websites either carry claims or links to websites making claims about the purported health benefits of consuming raw apricot kernels, including claims that consuming them can prevent or cure cancer. Some but not all have warnings in regard to the risk of cyanide poisoning. However, the warnings are sometimes confusing or contradictory in regard to the 'safe' quantity of consumption. For example, the quantity can be cited as 'more than 'three a day can be toxic' or suggested as 'take two every hour'.

Claims of cancer-related health benefits from raw apricot kernels are not supported by the Australian/New Zealand medical community or Cancer Council of Australia. There is no reliable scientific evidence or expert medical opinion to support them. While the Australian Competition and Consumer Commission (ACCC) successfully took court action against an apricot kernel retailer in 2009 for making misleading or deceptive claims, a variety of individuals and businesses continue to make these types of claims.

The use of raw apricot kernels by cancer patients raises FSANZ's concerns about the capacity of information alone to prevent harm, given the vulnerability of people who are fighting serious or terminal illnesses. The most recent poisoning incident occurred despite the presence of clear warning labels on the packaging and on the website from which the product was purchased.

However, on the basis of the decision making framework presented in the Council of Australian Governments Best Practice Regulation Guide, there is insufficient evidence to demonstrate that government intervention in the context of the alternative options presented in this RIS would result in a sufficiently notable reduction in the level of harm to consumers to offset likely costs to industry. On this basis, it is not possible to demonstrate a net benefit to the community as a whole from the alternative options considered in the RIS. Therefore, the RIS recommends the status quo option as preferred.

1 Introduction

Proposal 1016 was prepared to assess the public health risks of some foods derived from plants containing cyanogenic glycosides and to develop appropriate risk management strategies to manage these risks, including consideration of a need for food regulatory measures in the *Australia New Zealand Food Standards Code (the Code)*¹.

This Decision Regulatory Impact Statement (RIS) has been prepared to examine the costs and benefits of various options for managing potential public health or safety issues from consumption of raw apricot kernels in Australia and New Zealand.

Some plant-based foods contain cyanogenic glycosides which can pose potential risks to consumers. The toxicity of cyanogenic glycosides and their derivatives depends on the release of hydrocyanic acid (HCN) from plant tissue. This occurs either after damage to the plant or as a result of the action of gut bacteria in animals or humans after ingestion. The concentration of HCN in seeds varies widely (49 to 4,000 mg/kg, depending on whether skin on or off varieties are surveyed). In raw apricot kernels (the seed of the apricot) levels can reach toxic thresholds (Haque and Bradbury, 2002; Codex Committee on Contaminants in Foods, 2008²). These levels can be sufficiently high to cause death in humans and the amounts in any particular apricot kernel can be hard to predict or control.³

Apricot kernels are available as:

- **raw apricot kernels**
 - skin on (unhulled)
 - skin off (hulled)
- **apricot kernel derived products** (e.g. alcoholic beverages, oil, flavourings, stone fruit juices, marzipan, cakes, biscuits and confectionery derived from apricot kernels) where apricot kernels are used as an ingredient.

Throughout this report, the term 'raw apricot kernel' refers to the nut-like object found within the shell or stone of the common apricot, *Prunus armeniaca* either skin on or skin off.

Poisoning incidents following consumption of raw apricot kernels have been confirmed in Australia, New Zealand, Hong Kong, Canada, USA, United Kingdom and other European countries.

In light of these poisoning incidents and the results from a recent survey on cyanogenic glycosides in a range of plant-based foods⁴, Food Standards Australia New Zealand (FSANZ) prepared Proposal P1016.

¹ [Australia New Zealand Food Standards Code \(the Code\)](#).

² Haque MR, Bradbury JH (2002) Total cyanide determination of plants and foods using the picrate and acid hydrolysis methods. *Food Chemistry*, 77(1): 107–114.
Codex Committee on Contaminants in Foods. (2008) Discussion paper on cyanogenic glycosides. CX/CF 09/3/11. Rome: FAO/WHO.

³ It should be noted that almonds and almond products consumed in Australia are sweet almonds, which contain low levels of HCN and are safe to eat.

⁴ A survey of the levels of HCN in a variety of plant-based foods available in Australia and New Zealand was conducted as part of the Implementation Subcommittee for Food Regulation's (ISFR) Coordinated Food Survey Plan to determine whether there are any public health and safety concerns for the Australian or New Zealand populations arising from the consumption of these foods. The results of the survey can be accessed from the [FSANZ website](#).

Various foods containing apricot kernels as ingredients were analysed in the survey, including amaretti biscuits, almond finger biscuits, apricot jams, and apricot nectar. They were found to not pose any risks to public health and safety. None of the proposed options will impact on currently available food that contains apricot kernels as an ingredient. Therefore, this Decision RIS focuses just on raw (skin on and skin off) apricot kernels.

FSANZ has made considerable effort to engage with and understand the raw apricot kernel industry, but the collected information was not sufficient for detailed quantitative analysis of the proposed options. Therefore, much of the analysis that has been done is qualitative and as a result some uncertainties are attached to its findings.

This Decision RIS has been prepared in accordance with COAG best practice regulation requirements, and includes the following sections:

- a statement of the problem – explaining the need for government action
- a statement of the objectives of any intervention
- a statement of the possible options to address the problem
- an impact analysis of the options
- details of the consultation undertaken
- a clear statement as to which is the preferred option and why
- details of how the preferred option would be implemented, monitored and reviewed.

A summary of reported poisoning incidents in Australia and New Zealand is included in Attachment 1 and a summary of poisoning incidents in other countries is included in Attachment 2. Also in the attachments is detailed information on consultation with stakeholders in 2012 (Attachment 3), September 2013 (Attachment 4), November 2013 (Attachment 5) and 2014–2015 (Attachment 6). A summary of submissions and FSANZ's responses from the Approval Report is provided in Attachment 7. The World Trade Organisation (WTO) notification is provided in Attachment 8.

2 The problem

The problem this Proposal seeks to address is the potential health outcomes of cyanide poisoning caused by consumption of raw apricot kernels, which, if the levels of HCN are high enough, can include death. General symptoms of sub-lethal doses have been reported as abdominal pain, headache, dizziness, short-term memory loss, confusion, flushing, palpitations and general illness.

The risk assessment undertaken by FSANZ indicated that consumption of raw apricot kernels, both skin on and skin off, poses an unacceptable acute risk to public health and safety for consumers due to cyanide poisoning.

FSANZ requested data on poisoning incidents from both Australian and New Zealand poisons information centres. Data shows that in the past 10 years there have been around 180 calls to poison information centres following either accidental (children and adults) or intentional ingestion (by adults only) of raw apricot kernels (Attachment 1).

In May 2011 a consumer in Queensland was hospitalised after consuming raw apricot kernels with high levels of HCN. In addition, there have been a number of confirmed reports of poisoning incidents in other countries following consumption of raw apricot kernels (Attachment 2). In July 2014, another consumer in Western Australia was hospitalised after consuming apricot kernels, despite the presence of the statement on the FSANZ website and

advice on the product package and website where the product was purchased. The product was recalled from the market due to high HCN levels (i.e. >3000 mg/kg)⁵.

Raw apricot kernels (skin on) are consumed intentionally for a therapeutic purpose and for perceived health benefits by some consumers. Also some consumption may be unintentional, due to kernels resembling almonds.**Error! Bookmark not defined.** It is assumed that buyers of large amounts (1 kg bags) are more likely to be those who are taking apricot kernels for their perceived health benefits. It is assumed that those using apricot kernels in home cooking (such as jam making) would tend to use small quantities that could be obtained from fresh apricots as they are typically only a small component by volume of receipts.

Domestically produced and imported raw apricot kernels are available in Australia and New Zealand.

Raw apricot kernels are available for purchase in health food stores, Asian grocery stores and a range of websites (such as online health food stores, eBay, etc.). FSANZ understands they are mostly purchased online. The websites either carry claims or links to websites carrying claims about the purported health benefits of consuming raw apricot kernels including claims that consuming them can prevent or cure cancer. Some but not all websites have warnings in regard to the risk of cyanide poisoning and the claims are sometimes confusing or contradictory in regard to the 'safe' quantity of consumption. For example, the quantity can be cited as 'more than three a day can be toxic' or suggested as 'two every hour' is the appropriate amount to consume.

The claims of health benefits from consuming raw apricot kernels have not been proven and there is no reliable scientific evidence or expert medical opinion to support them.⁶

In 2009, the Australian Competition and Consumer Commission (ACCC) successfully took court action against a business/individual in regard to misleading claims. The business suggested that a treatment program they were promoting was effective in the treatment of cancer by ingesting high levels of Laetrile⁷ (also known as Amygdalin) sourced in such foodstuffs as raw apricot kernels. However, an expert oncologist engaged by the ACCC, whose evidence was accepted by the court, indicated that high levels of Laetrile can result in cyanide toxicity. The Brisbane Federal Court ruled that the business/individual engaged in misleading or deceptive conduct in relation to certain cancer prevention and treatment claims. The ACCC chairman stated that the ACCC acted in the public interest to protect vulnerable people who are fighting serious or terminal illnesses.⁸

While actions taken by ACCC have been helpful (e.g. some online sellers no longer directly make claims on their site), there is still a problem as some sellers link to other websites with claims.

The ACCC actions are predicated on misleading and deceptive claims. Whilst FSANZ is also concerned about misleading claims the issue of raw apricot kernel safety makes it a wider issue requiring a strong food regulatory measure from FSANZ.

⁵ Although the actual value was not confirmed (it was not relevant for the purpose of testing), this is the highest level measured in Australia and New Zealand. Any level above 3000 mg/kg could lead to exceedance of the acute reference dose (ARfD) or poisoning.

⁶ [Submission from Cancer Council Australia to FSANZ's Proposal P1016 - Hydrocyanic acid in Apricot Kernels & Other Foods](#)

⁷ [Cancer Tutor website](#)

⁸ <https://www.accc.gov.au/media-release/cancer-treatment-found-to-be-misleading>

FSANZ was advised by the state/territory jurisdictions (whose role it is to enforce the Code⁹) that the regulations in the Code were inadequate to take action against businesses when consumers experienced acute poisoning from consumption of raw apricot kernels. Recent examples are in Queensland and Western Australia. Although there are general safe and suitable provisions in the food acts, it is hard for jurisdictions to prove that food is unsafe because of the wide range of HCN in individual kernels.

The fact that raw apricot kernels are being used by cancer patients further raises FSANZ's concerns about the ability of information alone to prevent harm.

There is currently no standard in the Code for HCN levels in raw apricot kernels. However, to ensure safe consumption the Code sets maximum levels of HCN for some foods or has other specific requirements for preparation of specific foods (such as sweet cassava, bamboo shoots, confectionery, stone fruit juices, marzipan, ready-to-eat- cassava chips).

A range of measures have been adopted overseas to manage the risk of poisoning incidents from raw apricot kernels. These include:

- The USA prohibits the sale of apricot kernels as a food since they are regulated as a drug (laetrile (amygdalin)) under import legislation (USA)¹⁰.
- The 28 member states of the European Union (EU) make it an offence to sell or possess for sale food which is injurious to health. Apricot kernels with very high HCN levels would be captured within the scope of the EU Food Safety Regulations.
- The United Kingdom and Canada provide advice for consumers on a recommended maximum number of apricot kernels to be consumed per day.

In Australia, the only state that regulates Laetrile (amygdalin) is Queensland, although this is not applicable to apricot kernels or other foods containing cyanogenic glycosides¹¹.

This RIS examines the case for government intervention due to the serious health risks of consuming raw apricot kernels, with children particularly vulnerable. The purpose of the following analysis is to determine whether an appropriate non-regulatory or regulatory intervention exists to better manage potential public health or safety issues from consumption of raw apricot kernels in a way that can be shown to be likely to result in a net benefit to the community as a whole.

3 Objectives

FSANZ's main objective under the Act is protection of public health and safety. This is the key principle in considering any food regulatory measure for Australia and New Zealand. FSANZ has taken an independent risk assessment with the principal objective of this proposal being whether measures can be put in place that will better assure and manage potential public health or safety issues from consumption of raw apricot kernels in a way that reduces risk to consumers while being mindful of costs to industry.

⁹ [Australia New Zealand Food Standards Code \(the Code\)](#)

¹⁰ The USA does not have any formal limits on HCN in foods. They previously took a case-by-case approach and if the product was marketed as food, they looked at it from the perspective of whether it contains excessive levels of cyanide that may render the food injurious to health and enforced on that basis. However, in 1977 the USA considered apricot kernels to be "laetrile" (also known as amygdalin) and now detain it as a new drug under relevant import legislation [Import Alert 62-01](#).

¹¹ In Queensland, oral amygdalin is not permitted and special approval is required to obtain, possess and use intravenous or intramuscular preparations. Approval is only considered for patients with an advanced malignancy where all possible conventional treatment has been exhausted.

4 Options

In order to decide on the most cost-effective approach to achieving these objectives, this proposal considers five options.

4.1 Option 1 – Maintain the status quo

Under the status quo FSANZ would rely on the current website advice which describes the number of raw apricot kernels that can be safely consumed per day.

FSANZ has produced an advisory statement, published on the FSANZ website, which highlights that it is unsafe for adults to consume more than three raw apricot kernels per day.¹² The statement advises that children should not eat any raw apricot kernels.

4.2 Option 2 – Mandatory labelling

This regulatory option considers whether labelling could appropriately manage the public health and safety risk associated with the consumption of raw apricot kernels. Labels on packages of apricot kernels would have a statement relating to the risk associated with consuming the product.

4.3 Option 3 – Set a maximum level of HCN

This regulatory option involves setting a maximum level (ML) in Standard 1.4.1 – Contaminants and Natural Toxicants for HCN in raw apricot kernels.

4.4 Option 4 – Prohibition on the sale of raw skin on apricot kernels

This regulatory option involves preparation of draft variations to prohibit the direct retail sale of raw skin on apricot kernels only in Standard 1.4.4 – Prohibited and Restricted Plants and Fungi. Businesses could continue to sell raw skin off apricot kernels. In addition, foods containing apricot kernels as ingredients that are safe for consumption (as a result of processing or treatment) would be exempt from the prohibition. In parallel, manufacturers would be required to provide advice for consumers on the maximum amount of raw skin off apricot kernels that could safely be consumed on their product labels.

This option allows the continued sale of raw skin off apricot kernels. However, as the HCN level varies considerably (49 to 440 mg/kg) in tested skin off kernels, there would be advice provided on FSANZ's website and on labels on the recommended maximum amount/day of skin off apricot kernels that could be safely consumed.

4.5 Option 5 – Prohibition on the sale of raw apricot kernels

This regulatory option involves preparation of draft variations to prohibit the sale of all raw apricot kernels as a food in Standard 1.4.4. Foods produced using raw apricot kernels as an ingredient would be exempted from this prohibition where they have undergone processing or treatment that renders them safe for human consumption.

The prohibition would also not apply to:

- whole apricots containing raw apricot kernels

¹² [FSANZ website](#)

- the use of whole apricots containing raw apricot kernels as an ingredient in a food (e.g. jam made using whole apricots).

The prohibition would not apply to the sale of raw apricot kernels to businesses for further processing. For example, wholesalers would be able to sell raw apricot kernels to manufacturers of biscuits that use apricot kernels as an ingredient in their products. Non-food uses are also not affected by this proposal (such as cosmetics).

5 Impact analysis

5.1 Affected parties

Parties that have been identified as potentially being affected by this Proposal include:

- industry (importers, producers and retailers)
- consumers of raw apricot kernels
- government.

Based on the information provided by four businesses¹³ in 2013¹⁴, FSANZ has produced the following estimates:

- approximately 20,000 kg of raw apricot kernels are imported into, or produced in, Australia for human consumption per year
- the average retail price is approximately \$30 per kilogram
- these figures suggest the total retail value of raw apricot kernel sales is approximately \$600,000 per year in Australia.

FSANZ has not received any import/production figures from New Zealand businesses selling apricot kernels. Consequently, FSANZ has no information on the volume of raw apricot kernels sold in New Zealand per year. However, the New Zealand Ministry for Primary Industries has informed FSANZ that between 2011 and 2013 there was an average of 264 kg of raw apricot kernels imported into New Zealand. In 2014, approximately 1,280 kg were imported; the increase due to a single shipment from Turkey.

More detailed information in relation to targeted consultation with industry to date is included in Attachments 3, 4 and 5.

5.2 Option 1 – Maintain the status quo

FSANZ would maintain the status quo and rely on the current website advisory statement which describes the number of raw apricot kernels that can be consumed by adults without harm, noting that children should not consume any.

The continuing sale of raw apricot kernels as health food is of major concern given the risk of poisoning and death. There is no reliable scientific evidence that the use of Laetrile¹⁵ through consumption of raw apricot kernels is effective in the treatment or prevention of cancer.

¹³ All four businesses are wholesalers based in Australia. Two of the four businesses also retail apricot kernels. The number of retail businesses the four businesses reported supplying to ranged from six to 3,000. The figure of 3,000 was reported to FSANZ from an importer/domestic producer of raw (skin on) apricot kernels.

¹⁴ This information was gathered from a survey sent to 46 businesses in both Australia and New Zealand.

¹⁵ The names Amygdalin and Laetrile are often used interchangeably. The name vitamin B17 is also used to describe this compound, although it is not recognised as a vitamin.

Promoters claim that malignant cells contain an abnormally high number of enzymes that break down Laetrile and Amygdalin, and as a result the release of hydrocyanic acid kills cancer cells while normal cells are left unaffected (Milazzo, 2006; American Cancer Society, 2012). Another commonly advertised claim is that cancer is a vitamin deficiency, and that Laetrile is the missing vitamin B17, therefore claiming that consuming laetrile prevents the development of cancer. Any successes attributed to the above claims have been generated by individual cases, testimonials and through publicity, and are not based on scientific evidence. Moertel et al (1982) published the outcomes from a clinical trial supported by the National Cancer Institute into the effect of laetrile in combination with metabolic therapy for cancer patients. Among the 175 cancer patients, only one case reported a partial response (reduction in tumour size) while three others claimed symptomatic improvement. Fifty-four per cent of participants had measurable tumour growth after three months of treatment, and by seven months all had reported tumour progression (Moertel, 1982). In addition, several patients with cyanide toxicity saw a reduction of related symptoms when Laetrile treatment was discontinued. Based on these outcomes (Moertel, 1982), the National Cancer Institute deemed Laetrile a toxic drug. It also concluded that Laetrile in combination with metabolic therapy is of no substantive value in the treatment of cancer.¹⁶

A systematic review into the effectiveness of Laetrile interventions as a cancer treatment in humans found no randomised controlled trials had been conducted. Milazzo et al. (2006) concluded that claims of Laetrile's therapeutic benefit for cancer patients are not supported by sound evidence.¹⁶

The status quo would likely have the following outcomes:

- The consumption of raw apricot kernels would continue, including health risk to consumers, particularly children, due to high levels of HCN.
- A lack of scientific evidence for the use of raw apricot kernels for cancer treatment as well as the risk to public health.
- Effectiveness of website advice may be limited, as it is dependent on consumers seeking and being aware of this information.
- There will be costs to the government in managing future incidents and health treatments.
- Consumer protection agencies will continue to use existing powers in order to prevent any business involved in misleading and deceptive conduct.

5.3 Option 2 – Mandatory labelling

FSANZ has considered whether mandatory labelling could appropriately manage the public health and safety risk associated with the consumption of raw apricot kernels.

Labels might have some (limited) impact on behaviour. However, it is dependent on consumers seeking and noticing and taking action on this information.

FSANZ views labelling for this issue as an inappropriate risk management option for the following reasons:

- Labelling is not an effective measure in mitigating a potentially serious public health risk for the general community where public awareness of the risk is low.

¹⁶ [Cancer Council Australia Submission](#)

- The most recent poisoning incident in Western Australia occurred despite the presence of clear warnings on the packaging and the website from which the product was purchased. This suggests labelling may not be sufficient to deter some consumers from consuming quantities of apricot kernels that can cause harm to them.
- The variability in the HCN levels and in particular maximum limits of HCN means that, similar to Option 1, it is impossible to predict a safe number of kernels that could be consumed per day. This variation means that it would be impractical to determine a labelling statement that would address the acute public health implications for all potential consumers. Furthermore, any advice on maximum consumption could become out of date as more information becomes available on the maximum levels which may occur.¹⁷.

There are identified acute dietary risks (exceedance of the acute reference dose (ARfD) of 80 µg HCN/kg body weight) and a potential for severe acute cyanide poisoning associated with the consumption of raw apricot kernels. This is supported by multiple published cases of adult and child cyanide poisoning resulting from eating raw apricot kernels. Even when only a small number of kernels are consumed, there is still the potential for consumers to exceed the ARfD and suffer poisoning when HCN levels in the apricot kernels are high.

Raw apricot kernels consumed by the hospitalised consumer in Queensland were reported as having levels of HCN of 2300mg/kg. This is consistent with previous reports of raw apricot kernels having average HCN levels of 1450 mg/kg, although internationally there have been reports of up to 4090 mg/kg of HCN. The fact that we import a significant percentage of raw apricot kernels from overseas and the limited size of sampling to date would suggest that these higher levels are definitely possible in the Australian and New Zealand food supply. In the most recent case, raw apricot kernels consumed by the hospitalised consumer in Western Australia were reported as having levels of HCN above 3000 mg/kg, which is the level where consumption of just one kernel is likely to lead to exceedance of the ARfD (80 µg HCN/kg body weight), particularly for children.

Therefore, the general availability of raw apricot kernels, including for children (which are the group at greatest risk of exceeding safe doses) means that relying on specific labelling statements may not provide adequate public health and safety protection.

If mandatory labelling is required, average cost of a labelling change would be somewhere around \$5,624.¹⁸ per single stock keeping unit (SKU).¹⁹

5.4 Option 3 – Set a maximum level of HCN

This regulatory option involves setting a maximum level (ML) in Standard 1.4.1. An ML is usually established where it serves an effective risk management function, at a level which is both:

- consistent with the protection of public health and safety
- is reasonably achievable.

Therefore, FSANZ considered whether an ML option would be appropriate for raw apricot kernels.

¹⁷ At the time of the first poisoning incident in Queensland, FSANZ's advice was to consume no more than four kernels per day. However, due to more recent data from the ISFR survey, that advice now needs to be updated to advise consumers of the reduced number of kernels that can now be safely consumed.

¹⁸ [Cost Schedule for Food Labelling Changes](#) – 2014 PricewaterhouseCoopers Report commissioned by the Department of Health (Australia).

¹⁹ Stock keeping unit (SKU) - One product can have a number of SKUs. For example, Coca-Cola has number of SKUs - single cans (250ml and 375 ml), 250ml and 375ml multipacks (10, 20 and 30 cans), single bottles (600ml, 1l, 1.25l and 2l), bottle multipacks, etc.

The Implementation Subcommittee for Food Regulation's (ISFR) survey found that all apricot kernel samples analysed contained detectable levels of HCN. However, there was a significant difference and large variability in the range of HCN concentrations between individual skin on and skin off kernels. Levels of HCN in 18 skin on kernels ranged from 1,240–2,820 mg HCN/kg and for the ten skin off kernels tested a range of 49–440 mg HCN/kg was present.

Taking into account the ARfD of 80 µg HCN/kg body weight and potential serving sizes for apricot kernels, any ML that was set by FSANZ would likely be so low that very few apricot kernels would be compliant. Consequently, the practical effect of setting an ML would be very similar to having a prohibition on all raw apricot kernels. As such the impact on reducing future poisoning would probably be greater than the status quo.

However, Option 3, if implemented, would also impose a very high implementation and enforcement cost on governments in conducting ongoing surveillance of HCN levels in raw apricot kernels on the market.

FSANZ considers that it is inappropriate to set an ML, as it would not be an effective mitigation measure for HCN in raw apricot kernels, for the following reasons:

- The ML set by FSANZ would end up being so low that very few apricot kernels would be compliant and it would have the same practical effect as prohibition.
- The ML would need to be set significantly below the range (1,240 to 2,820 mg/kg) seen in the test samples⁴, as sample size was small. Therefore the risk may be underestimated based on current information.
- The wide variation in levels of HCN in raw apricot kernels would make any process control arrangements (including sampling plans) complex and difficult to achieve consistency in levels of HCN. This variability and uncertainty increases when considering the potential differences in the levels of raw skin on and skin off kernels.
- The FSANZ Risk Assessment was completed prior to the latest poisoning incident in Western Australia. The results of testing in that incident suggest that the levels of HCN in apricot kernels can be higher than those that were found in samples tested in the recent ISFR Survey.

5.5 Option 4 – Prohibition on the sale of raw skin on apricot kernels

This option allows the continued sale of raw skin off apricot kernels only. However, there would be advice provided on FSANZ's website on the amount of raw skin off apricot kernels that could be safely consumed per day. Additionally, mandatory labelling of raw skin off kernels would be required to advise consumers of the health risks of exceeding recommended consumption levels.

The costs and benefits relating to labelling are discussed under Option 2 above. The costs and benefits of prohibiting the sale of raw skin on apricot kernels are outlined in Table 1.

Table 1. Costs and benefits of Option 4 – Prohibition on the sale of raw skin on apricot kernels

| Affected party | Impacts |
|-------------------|---|
| Government | |
| Costs | Associated costs to enforce the prohibition of raw skin on apricot kernels. |
| Benefits | Gives certainty in enforcing the state and territory Food Acts (under the safe and suitable legislation). Partially reduces likelihood and subsequent health costs of further poisoning incidents caused by consumption of raw skin on apricot kernels. |
| Industry | |
| Costs | Immediate costs to profits and reduced revenue for industry on account of the removal of all raw skin on apricot kernels, which are not intended to be further processed before sale, from the market. Revenue loss might be reduced if consumers switch purchases to raw skin off kernels. |
| Benefits | Reduce the risk of food poisoning events from raw skin on apricot kernels and associated costs of such events. |
| Consumers | |
| Costs | Denies access to raw skin on apricot kernels for those consumers who seek to buy raw skin on apricot kernels. |
| Benefits | For consumers, a reduction in risk of dietary exposure to HCN from raw skin on apricot kernels and the associated negative health consequences. Avoids consumers' inappropriately purchasing raw skin on apricot kernels. |

This option was considered because there is a difference in the maximum concentration of HCN between skin on and skin off varieties. For the skin on kernels, a maximum level of HCN of 2,820 mg/kg from the ISFR survey was used in the risk assessment. Calculations showed that adults could consume only three kernels per day before the safe level is exceeded and that children would be at risk from consumption of only one kernel per day. In contrast, in the raw skin off kernels, the maximum level of HCN was 440 mg/kg and adults could consume 21 kernels per day and children could consume six kernels per day before the safe level is exceeded.

As most of the consumers that are taking apricot kernels for their (perceived) health benefits are using skin on apricot kernels, a reduction in the risk of future poisoning is likely to be high compared to the status quo.

However, due to the variability in HCN levels in both varieties, there is still considerable uncertainty in estimating maximum numbers that could be safely consumed (particularly for children) as there have been reports of up to 4,090 mg/kg of HCN in skin on varieties in the international scientific literature. As noted above, higher levels were found in the July 2014 Western Australia incident, indicating it is also likely that higher levels will be found in skin off varieties than was determined in the survey, meaning even a small number could cause adverse health effects. Therefore, it is unlikely that this option would provide comprehensive safeguards for consumers.

5.6 Option 5 – Prohibition on the sale of all raw apricot kernels

Option 5 is a prohibition on the direct retail sale of all raw apricot kernels in Standard 1.4.4, with an exemption for foods containing raw apricot kernels as an ingredient that are safe for consumption. The costs and benefits of this option are outlined in Table 2.

Table 2. Costs and benefits of Option 5 – Prohibition on the sale of all raw apricot kernels

| Affected party | Impacts |
|-------------------|--|
| Government | |
| Costs | Associated costs to enforce the prohibition. |
| Benefits | Gives certainty in enforcing the state and territory Food Acts (under the safe and suitable legislation). Reduces likelihood and subsequent health costs of further poisoning incidents. |
| Industry | |
| Costs | Loss of revenue and profits from the prohibition for sale of all raw apricot kernels, which are not intended to be further processed before sale. |
| Benefits | Reduce the risk of food poisoning events and associated costs of such events. |
| Consumers | |
| Costs | Denies access to raw apricot kernels for those consumers who seek to buy them. |
| Benefits | For consumers, a reduction in risk of dietary exposure to HCN from raw apricot kernels and the associated negative health consequences. Avoids consumers inappropriately relying on apricot kernels to prevent or cure cancer to the extent a secondary or black market is not developed. |

As we can see from private submissions, some consumers may feel aggrieved about losing access to raw apricot kernels. But this sense of loss is based on misleading information that consumption of raw apricot kernels assists in the prevention and cure of cancer and that as a ‘natural cancer therapy’ there are no harmful effects.

Laetrile, an extract from apricot kernels, was for years promoted as a natural alternative therapy for cancer. The Cancer Council of Australia advises that taking Laetrile, or eating raw apricot kernels in large amounts, is not only ineffective at treating cancer but could also cause fatal cyanide poisoning²⁰. The successes claimed by its supporters are based on individual reports, testimonials, and publicity issued by promoters. Concerns exist about individuals relying on this type of treatment alone, and avoiding or delaying conventional medical care for cancer. This could have serious health consequences²¹.

The consensus of available scientific evidence does not support claims that laetrile is an effective anti-cancer treatment either in animal studies or in human clinical trials. Given the lack of scientific evidence for the use of raw apricot kernels for cancer treatment as well as the risk to public health, the Cancer Council of Australia strongly welcomes and supports the prohibition on the sale of raw apricot kernels.¹⁶

²⁰ [Consumer advice website](#) administered by the Cancer Council Australia:

²¹ [American Cancer Society - http://www.cancer.org/](http://www.cancer.org/)

The intent of Option 5 is not to prohibit the use of raw apricot kernels for safe uses as an ingredient in other foods (such as confectionery), nor does it prohibit the sale of whole apricots containing raw apricot kernels. Businesses will still be able to sell raw apricot kernels to other businesses for further processing. FSANZ does not regulate the use of kernels in cosmetic products, which are unaffected by this proposal.

It is acknowledged that kernels may be currently purchased for home-cooking by consumers or possibly for catering use, although we believe this market is very limited. It is assumed that those using apricot kernels in home cooking (such as jam making) would tend to use small quantities that could be obtained from fresh apricots. Therefore loss of availability of this ingredient is likely to be of minor impact.

Most of the raw apricot kernels (skin on and skin off) are purchased online. FSANZ asked both the New Zealand Commerce Commission (NZCC) and the Australian Competition and Consumer Commission (ACCC) for their views regarding actions that they may take against the sale of raw apricot kernels, specifically, sales via the internet sites which make misleading or unsubstantiated claims.

The NZCC indicated that it would have jurisdiction over overseas sites advertising goods such as apricot kernels where they ship to New Zealand, but it is more difficult due to businesses not having a physical location in New Zealand. The NZCC uses broad criteria to justify further investigation, such as: extent of harm (how widespread); seriousness (history of harm); and whether it is in the public interest to intervene. In the case of advertising of apricot kernels, the NZCC indicated it would require evidence that misleading claims were occurring before it would prioritise this as an issue that required further screening and follow up.

The ACCC considers all potential enforcement matters against its Compliance and Enforcement Policy²² on a case-by-case basis.

The Compliance and Enforcement Policy includes a number of factors to determine enforcement priority such as evidence of substantial harm to consumers demonstrating substantial consumer detriment is one of the factors considered. Another factor is whether the relevant regulator has the necessary powers to deal with the issue within their own legislation. If a substance is already a prohibited food, then the ACCC would consider whether the relevant States, Territories and New Zealand could deal with the matter through their own Food Acts.

In the case of a product making cancer cure claims, if the concern is that a harmful substance is being used because therapeutic claims are being made or it is generally perceived to be for therapeutic use, the ACCC would consider whether the Therapeutic Goods Administration (TGA) could respond through its own Act and Regulations.

The ACCC has, at times, taken enforcement action in relation to both foods and therapeutic goods as these can also fall under the definition of consumer good. If there was a genuine public health emergency the ACCC would certainly consider whether the Competition and Consumer Act 2010 could be used to protect consumers.

Note that while actions taken by ACCC have been helpful (for example some online sellers no longer directly make claims on their site), there is still a problem as sellers continue to link to other websites with similar claims.

²² [Compliance and Enforcement Policy](#), ACCC website

5.7 Comparison of options and conclusion

The determination of which option is likely to have the greatest net benefit is based on qualitative analysis. Despite considerable consultation with stakeholders, FSANZ has not received sufficient data to include a more extensive quantitative analysis in this Decision RIS.

None of the proposed alternative options would reduce risk to zero and most will impose additional costs especially to industry. On the basis of the decision making framework presented in the Council of Australian Governments Best Practice Regulation Guide, there is insufficient evidence to demonstrate that a government intervention on the basis of the alternative options presented in the RIS would result in a notable reduction in the level of harm. On this basis, it is not possible to demonstrate a net benefit to the community as a whole from the alternative options presented and this RIS therefore recommends the status quo as the preferred option.

Table 3 presents a comparison of the various options and their implications for the sale of raw apricot kernels, apricot kernel derived products and whole apricots. Only Option 5 prohibits the direct retail sale of all raw apricot kernels.

Table 3. *Implications for the sale of apricot kernels and products according to different regulatory options*

| | Option 1 ²³ | Option 2 ²⁴ | Option 3 ²⁵ | Option 4 ²⁶ | Option 5 ²⁷ |
|---|------------------------|------------------------|------------------------|------------------------|------------------------|
| Direct retail sale of raw skin on apricot kernels as food | Yes | Yes | Yes ²⁸ | No | No |
| Direct retail sale of raw skin off apricot kernels as food | Yes | Yes | Yes | Yes | No |
| Wholesale of raw skin on apricot kernels | Yes | Yes | Yes | Yes | Yes |
| Wholesale of raw skin off apricot kernels | Yes | Yes | Yes | Yes | Yes |
| Processed foods derived from apricot kernels (provided that a processing or treatment step is undertaken to render the food safe for human consumption) | Yes | Yes | Yes | Yes | Yes |
| Whole apricots which contain raw apricot kernels | Yes | Yes | Yes | Yes | Yes |

²³ Option 1: Maintain the status quo

²⁴ Option 2: Mandatory labelling of all raw apricot kernels

²⁵ Set a maximum level of HCN all raw apricot kernels

²⁶ Option 4: Prohibition on the sale of raw skin on apricot kernels with exemptions for raw apricot kernel-derived foods that are safe for consumption. In parallel, require manufacturers to provide advice for consumers on the maximum amount of raw skin off apricot kernels that could safely be consumed on their labels.

²⁷ Option 5: Prohibition on the sale of all raw apricot kernels. The prohibition covers both skin on and skin off kernels but foods containing apricot kernels as an ingredient that have undergone processing or treatment to render them safe for human consumption would be exempted from the prohibition.

²⁸ Provided that HCN levels are below ML levels set in the Food Standards Code.

6 Commonwealth Regulatory Burden Measure

FSANZ is subject to the Australian Government's cutting red tape agenda and as such we comply with the requirements of the Regulatory Burden Measurement framework. This framework notes that where the Commonwealth does not have 100 per cent control over the governance or regulatory arrangements, the threshold for 'level of Commonwealth involvement' is interpreted as the existence of a funding agreement or a degree of influence (such as involvement in a ministerial council). The exact portion is determined on a case-by-case basis.

In this case, as the recommended option is the status quo, there is no change to compliance costs.

7 Consultation

7.1 Targeted consultation

From the commencement of this Proposal, FSANZ has made considerable efforts to engage with the raw apricot kernel industry, state and territory government agencies, and consumers. FSANZ utilised public and targeted consultation throughout the development of this project to identify and understand the raw apricot kernel industry and develop better regulation. However, ongoing difficulties have been experienced in obtaining sufficient information for detailed quantitative analysis of the proposed options.

In April 2012, a targeted consultation seeking data and/or information on the nature of the industry, its size and the costs of production or importation for raw apricot kernels was undertaken with four apricot kernel businesses identified by an online search. Identified businesses were approached via email. FSANZ received two responses (see Attachment 3).

In September 2013, a letter was sent out to 46 importers, producers and retailers in Australia and New Zealand to invite participation in FSANZ's considerations for this Proposal. FSANZ received four responses (see Attachment 3), all from Australian businesses.

In November 2013, a detailed questionnaire was sent to 46 businesses in both Australia and New Zealand. FSANZ received eight responses; seven of them from Australia (see Attachment 5). Two businesses indicated that they no longer imported apricot kernels (this included the only New Zealand business that responded). One business only imported apricot kernel oil²⁹. One importer indicated that they would provide some information, but to date no response has been received. Four other businesses (all from Australia) provided their import/production numbers, costs and other information. All four of these businesses were wholesalers. The number of retail businesses that these wholesalers reported supplying to range from six to 3,000 retail businesses. Two of the four wholesale businesses also sold apricot kernels directly to the public.

As noted in the Impact Analysis (under Affected Parties), based on the survey responses FSANZ estimates that the total turnover of the raw apricot kernel industry is approximately \$600,000 per year in Australia. This is based on approximate sales volumes of 20,000 kg per year and an average retail price of \$30 per kilogram.

More detailed information in relation to targeted consultation with industry to date is included in Attachments 2, 3, 4 and 5. This work has informed the development of the options

²⁹ They have a requirement from their suppliers that Apricot kernel oil is hydrocyanic acid free.

explored in this Decision RIS, but the collected information was not sufficient for the detailed quantitative analysis of the proposed options.

From December 2014 to February 2015 further consultation was also undertaken with stone fruit manufacturers, Horticulture Australia, Horticulture New Zealand, canning and dried fruit manufacturers as part of the process of developing the evidence base for the Decision RIS (Attachment 6).

Further consultation was also undertaken with government enforcement agencies to discuss issues raised by jurisdictions and by China (as part of the WTO notification) during the public consultation period, from 16 December 2014 to 10 February 2015.

7.2 Summary of issues raised in submissions

The Call for Submissions was released for public consultation from 16 December 2014 to 10 February 2015. Twenty-three submissions were received from the following organisations (Attachment 7):

- Food Technology Association of Australia
- Almond Board of Australia
- Australian Nut Industry Council & Nuts for Life
- Weston A Price Foundation
- New Zealand Ministry for Primary Industries
- Department of Health Victoria
- New Zealand Food & Grocery Council
- NSW Food Authority
- Queensland Health
- CHOICE
- Cancer Council Australia
- Twelve private submissions
- AQSIQ Wenkang Sun WTO submission China.

Many issues were raised in these submissions, not all of which are relevant to this RIS. Eight submissions supported the proposed prohibition with some raising broader issues for consideration by FSANZ and making comments on the draft variation. Two submitters were non-committal, and the remaining 13 submitters were opposed to the prohibition.

Submitters in support agreed that there were public health and safety issues with consumption of apricot kernels and that a prohibition was needed to prevent businesses profiting from the spread of misinformation on the health benefits of apricot kernels and the sale of a dangerous food.

In contrast those opposed to the prohibition, particularly private submitters thought that apricot kernels had therapeutic value or health benefits and that FSANZ should not prohibit these foods but leave the responsibility with consumers. They argued that the prohibition was too draconian and that generic labelling was more appropriate so as to preserve consumer choice.

As outlined in Attachment 7, FSANZ has made some changes to the draft variation in response to submitter comments to the Call for Submissions. The main change is the removal of a list of products which were to be exempted from the prohibition on the sale of

raw apricot kernels or substances derived therefrom³⁰. The revised draft variation would still prohibit the sale of raw apricot kernels as a food to consumers. Products containing raw apricot kernels would be prohibited unless they were subject to processing or a treatment that rendered them safe for human consumption. This exemption would enable manufacturers of products such as alcoholic beverages, biscuits and jams that contain apricot kernels to continue to sell their products.

Also, as members of the World Trade Organisation (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and where the proposed measure may have a significant effect on trade (see Attachment 8).

8 Implementation and review

As the status quo is being recommended in the RIS, consideration of any implementation or review is unnecessary at this stage.

9 References

Australian Competition and Consumer Commission (ACCC) court action against a business/individual in regard to misleading claims. Available on the [ACCC website](#).

Australia New Zealand Food Standards Code. Available on the [Food Standards website](#).

Cancer Council Australia submission to FSANZ's Proposal P1016 - Hydrocyanic acid in Apricot Kernels & Other Foods Available on the [Cancer Council Australia website](#).

Cancer Council Australia - [Consumer advice](#).

Codex Committee on Contaminants in Foods. (2008) Discussion paper on cyanogenic glycosides. CX/CF 09/3/11. Rome: FAO/WHO

FSANZ (2011) FSANZ advice for consuming raw apricot kernels available on the [Food Standard website](#).

FSANZ (2014) Survey of cyanogenic glycosides in plant-based foods in Australia and New Zealand 2010–13. Available on the [Food Standard website](#).

Haque MR, Bradbury JH. (2002) Total cyanide determination of plants and foods using the picrate and acid hydrolysis methods. *Food Chemistry*. 77(1): 107-114.

Lasch, et al. (1981) Multiple cases of cyanide poisoning by apricot kernels in children from Gaza. *Pediatrics* 68: 5-7

Milazzo S, Lejeune S, Ernst E. Laetrile for cancer: a systematic review of the clinical evidence. *Support Care Cancer*. 2007; 15, 583 – 595.

³⁰ These exempted products were: alcoholic beverages, oil, flavourings, stone fruit juices, marzipan, cakes, biscuits, and confectionery. The ISFR survey found no samples of foods containing apricot kernels as an ingredient in which HCN levels were of concern. The ISFR testing included amaretti biscuits, almond finger biscuits, apricot jams, and apricot nectar.

Moertel CG, Fleming TR, Rubin J, Kvols L, Sarna G, Koch R, Currie VE, Young CW, Jones SE, Davignon JP. A clinical trial of amygdalin (laetrile) in the treatment of human cancer. *NEJM*. 1982; vol. 306, no.4, 201-206.

PricewaterhouseCoopers Report commissioned by the Department of Health (Australia) – Cost Schedule for Food Labelling Changes (2014) – Available on the [Department of Health website](#).

Sayre JW, Kaymakcalan S. (1964) Cyanide poisoning from apricot seeds among children in Central Turkey. *N Engl J Med*. 270:1113–1118

UK Food Standards Agency (UKFSA) warns against consuming raw apricot kernels. Available on [The National Archives website](#).

US Food and Drug Administration - Import Alert 62-01. Available on the [U.S. Food and Drug Administration website](#).

Attachment 1 – A summary of reported poisoning incidents from raw apricot kernels in New Zealand and Australia

It has been suggested that acute HCN poisoning is qualitatively similar between children and adults, but children may be more vulnerable than adults to poisoning from some sources.³¹

FSANZ found two publications describing lethal consequences from consumption of raw apricot kernels:

- Sayre and Kaymakcalavu (1964) report that between 1957 and 1962, two children died of cyanide poisoning in a hospital in Central Turkey after eating raw apricot kernels. No information was provided on how many kernels were consumed.³²
- Lasch and Shawa (1981) report two more deaths of children in Gaza. One had been part of a group that had been “feasting on apricot kernels,” according to their parents, and another had consumed a sweet prepared from raw apricot kernels. Once again, there was no information on how much was consumed.³³

Recently, FSANZ requested data on poisoning incidents from both Australian and New Zealand poisons information centres. Data clearly show that there have been a number of calls to poison information centres following either accidental (children and adults) or intentional ingestion (by adults only) of raw apricot kernels.

Table 4. *New Zealand Poisons Information Centre (1 January 2003 to 1 February 2013)*

| Circumstances | Total number of calls/reports on poisons centres' databases | Further information |
|---|---|--|
| Adult intentional | 4 | Adults ingested a large number of raw apricot kernels as an alternative medicine and developed symptoms of cyanide toxicity: abdominal pain, headache, dizziness, short-term memory loss, confusion, flushing, palpitations and general illness. The then New Zealand Food Safety Authority managed these incidents by providing general advice on consumption of apricot kernels. |
| Adult unintentional | 9 | Accidentally ingested as part of a kernel or a whole kernel intact. |
| Child unintentional (accidental or exploratory) | 7 | |
| Total | 20 | |

³¹ [National Center for Biotechnology Information website.](#)

³² [Sayre and Kaymakcalavu \(1964\)](#)

³³ [Lasch and Shawa \(1981\)](#)

Table 5. VIC Poisons Information Centre (1 May 2005 to 6 February 2014)

| Circumstances | Total number of calls/reports on poisons centres' databases | Further information |
|---|---|---|
| Adult intentional | 15 | Taken as a cancer treatment. Three cases of poisoning reported with symptoms of cyanide toxicity reported as 'grey-looking', lightheaded, loss of consciousness, nausea and vomiting. |
| Adult for reasons other than cancer treatment | 12 | One caller said he was taking the kernels for 'health benefits'; another said she was taking them 'as a tonic'; the others did not specify why they were taking them. |
| Child unintentional (accidental or exploratory) | 6 | |
| Total | 33 | |

Table 6. NSW Poisons Information Centre (1 January 2004 to 5 January 2014)

| Circumstances | Total number of calls/reports on poisons centres' databases | Further information |
|---|---|--|
| Adult intentional | 11 | As a cancer treatment. Reported as ingesting between 20–50 kernels in a few hours or a number of kernels daily over a period of weeks or years to treat cancer. General symptoms of cyanide toxicity: swelling of face, increased heart rate, vomiting, difficulty breathing, and dizziness. Some callers advised to attend hospital immediately, particularly those that had ingested 30 or more kernels. |
| Adult unintentional or other than cancer treatment or unknown | 26 | To improve general health, accidental (e.g. mistaken for almonds or using kernels in a home-made jam recipe) or reasons unknown. Reported as ingesting some, few, handful or specific amounts (2–30) of raw apricot kernels. |
| General queries | 27 | General queries for advice and concerns about or following consumption of apricot kernels (including recalls) to NSW poison information centre. |
| Child unintentional (accidental or exploratory) | 13 | Children (accidental) were asymptomatic but reported as sucked on a kernel, ingested a bit of a kernel or 1 whole kernel consumed. |
| Total | 77 | |

Table 7. WA Poisons Information Centre (23 March 2002 to 31 August 2013)

| Circumstances | Total number of calls/reports on poisons centres' databases | Further information |
|---|---|--|
| Adult intentional | 7 | Used as a complementary medicine, or suicide or other reasons. Reported as ingesting 20–40 kernels and lead to neurological, cardiovascular or gastrointestinal symptoms. |
| Adult unintentional | 11 | Accidental food poisoning. Reported as ingesting between 1 to 20 apricot kernels |
| Adult unknown | 2 | |
| Child intentional | 2 | 2 children were fed ground up apricot kernels by the mother over several months. There was a concern as both children were losing weight. Strongly recommend for a medical review. |
| Child unintentional (accidental or exploratory) | 4 | Generally reported as ingesting 1 whole kernel |
| Total | 26 | |

Table 8. QLD Poisons Information Centre (January 2003 to February 2013)

| Circumstances | Total number of calls/reports on poisons centres' databases | Further information |
|---|---|--|
| Adult intentional | 9 | Ingestion of apricot kernels as an alternative medicine (8) and deliberate self-poisoning (1) Amounts consumed varied from a single apricot kernel swallowed whole to 20 kernels a day for 4 weeks Symptoms reported: stomach upset and cramps, flushed, breathing problems, swollen face, headache, light headedness, confusion, numbness in feet. No patient outcomes are available |
| Adult unintentional (accidental) | 4 | |
| Child unintentional (accidental or exploratory) | 1 | |
| Total | 14 | The number of patients (includes all patient types) that were symptomatic= 11 |

Attachment 2 - Poisoning incidents from consumption of HCN in apricot kernels in other countries

Raw apricot seeds contain cyanogenic glycosides which cause poisoning and death when eaten raw and in sufficient amounts. Cases of poisoning from apricot seeds have been reported in the medical literature since the 1960s. The first reported cases of cyanide poisoning due to apricot seed ingestion were nine children in Turkey in 1957 (Sayre, 1964) which included two deaths. Twenty-four cases of cyanide poisoning in children were also reported in 1981 in Gaza with three deaths due to apricot seed ingestion (Lasch, 1981).

1.1 Canada

There have been a limited number of reports of adverse symptoms experienced by Canadians who have consumed raw apricot kernels. Sometimes, but not always, these reports result from the consumption of raw apricot kernels for medicinal or natural health purposes, the use of which has not been evaluated or approved by Health Canada.

In Canada one man died in 2000, after consuming 20 to 40 gelatin capsules containing crushed bitter raw apricot kernels on a daily basis over a three month period of time, as an alternative to cancer treatment. Two women were hospitalized after consuming bitter apricot kernels, one in June 2005 and one in May 2009.

The most recent Canadian poisoning incident occurred in May 2009, when a woman was hospitalised following the consumption of approximately 40 raw apricot kernels in a short period of time. This event prompted the posting of an advisory on [Health Canada's Advisory and Warnings website](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_101-eng.php) (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_101-eng.php).

Additionally, in 2009, Health Canada published a fact sheet on its [Food and Nutrition website](#) about cyanide in bitter apricot kernels.

Canada considered that consumer and industry education on the potential health risks associated with the consumption of large numbers of bitter apricot kernels was an appropriate method of communicating health risks at that time. The following excerpt from Health Canada's website presents Health Canada's opinion and consumer advice pertaining to bitter apricot kernels:

It is the opinion of Health Canada that apricot kernels should not be consumed for medicinal or natural health purposes. There is a concern about the potential health effects associated with large numbers of bitter apricot kernels being consumed on a regular basis, particularly by young children. Health Canada advises adults of the general population who do eat bitter apricot kernels as flavouring to consume no more than three bitter apricot kernels per day, ground and mixed with other foods.

1.2 United Kingdom

In 2006, the UK Food Standards Agency (UKFSA) Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)³⁴ expressed concern that, when ingested, bitter raw apricot kernels can produce cyanide. The COT therefore considered a safe intake is equivalent to [one to two kernels a day](#).

³⁴ [UK Food Standards Agency \(UKFSA\) Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment \(COT\) website](#).

1.3 Europe

Between 2005 and 2008, 15 notifications on cyanide in raw apricot kernels were transmitted through the Rapid Alert System for Food Feed (RASFF) database of the European Commission. The reported levels ranged approximately between 300-2500 mg/kg.

In order to make a notification under the RASFF system and protect public health and safety, Article 14(2)(a) of Regulation No (EC) 178/2002 is used which makes it an offence to sell or possess for sale food which is unsafe or injurious to health.

1.4 USA

Raw apricot kernels have long been recognized as a potential source of cyanide poisoning due to their cyanogenic glycoside (amygdalin) content. The most recent poisoning incident in the USA was in 2014 where an individual reported consuming apricot kernels and having symptoms such as dizziness, panting and convulsions.

The USA does not have any formal limits on HCN in foods. It previously took a case-by-case approach and if the product was marketed as food, they looked at it from the perspective of whether it contains excessive levels of cyanide that may render the food injurious to health and enforced on that basis. Their general advice in the past was that almond pastes and pastes made from other kernels should contain less than 25 ppm (mg/kg) of HCN naturally occurring in the kernels.

Currently, the USA considers raw apricot kernels to be "laetrile" (also known as amygdalin) and detain it as a new drug under relevant import legislation [Import Alert 62-01](#).

1.5 Hong Kong

In 2014 the [Department of Health](#) in Hong Kong issued a warning against consuming raw apricot seeds due to a case of poisoning in a 26 year old male. The patient developed abdominal pain, vomiting, dizziness and headache about two hours after consuming a self-prepared drink containing raw bitter apricot seeds.

Attachment 3 – Consultation with stakeholders 2012

Consultation with industry in April 2012

In April 2012, a targeted consultation was undertaken with four raw apricot kernel businesses (importers and retailers) identified by online search. Identified businesses were approached via email.

At that time, FSANZ asked two specific questions:

1. Do you import or produce raw apricot kernels in Australia or New Zealand?
2. What is the size of your production and/or imports and the associated costs of production of apricot kernels?

Responses were received from two businesses that both produce Australian grown apricot kernels. One business indicated that their raw apricot kernels are not being used as food and another business produces around seven tons of raw apricot kernels that are used as food.

One of the producers mentioned that they are also looking to import approximately 4–6 tonnes for certified organic raw apricot kernels to supply the Australian market. Organic raw apricot kernels are non-existent in commercial quantities in Australia so they stated that they need to look abroad to meet the demand in Australia for this popular food.

Attachment 4 – Consultation with stakeholders in September 2013

Letter to industry in September 2013

In September 2013, a letter was sent out to 46 businesses (importers, producers and retailers) in both Australia and New Zealand. Approached businesses were identified by online research and from customs import data. FSANZ received four responses (all from Australian businesses).

The purpose of this letter from FSANZ was to inform the raw apricot kernel industry about Proposal 1016 and invite them to subscribe to FSANZ standards management mailing list for P1016, and let them know that we will be calling for data and/or information to assist FSANZ in estimating impacts on industry.

Please see below a copy of the letter sent to raw apricot kernel businesses in September 2013.

Dear Sir/Madam

Food Standards Australia New Zealand (FSANZ) is a bi-national scientific government agency responsible for setting food standards in Australia and New Zealand.

FSANZ is currently progressing a Proposal (P1016) to identify potential public health and safety risks associated with the consumption of raw apricot kernels and food products derived from them. For more background information refer to the following websites: [Work Plan](#), FSANZ website and [Proposal P1016 - Hydrocyanic Acid in Apricot Kernels & other Foods, FSANZ website](#).

As part of our assessment, FSANZ will consider appropriate risk management strategies to manage any identified public health and safety risks. We are obliged to consider the potential benefits and costs that may result from any proposed food regulatory measures (non-regulatory or regulatory). There are a number of options that could achieve the desired outcome of protection of public health and safety and FSANZ will need to examine the regulatory impacts of each option.

These consist of:

- a non-regulatory approach (e.g. consumer education) that may incorporate advice on the recommended maximum number of apricot kernels/day)
- complete prohibition on the sale of raw apricot kernels with an exemption for safe food products derived from them
- setting a maximum limit (ML) for HCN in raw apricot kernels and if needed, for food products derived from them
- labelling (with advice on the maximum number of raw apricot kernels that could be consumed in a day without adverse health effects)

FSANZ expects to have completed its risk assessment and options for consideration by the FSANZ Board in December this year. We will be calling for data and/or information that can assist in estimating impacts on industry. While any data provided will be used to arrive at a general profile of the apricot kernel industry across Australia and New Zealand, you will not be identified as the source of information.

The information you provide will be treated in confidence and will not be published by FSANZ. However, the information may be subject to a freedom of information request once it is in FSANZ's possession. Exemptions to the release of data do exist. However, exemptions are qualified and businesses do not get a right of veto over disclosure.

Therefore, in order that you can assist FSANZ at the time of public consultation on this Proposal, we invite you to supply your details on our submitter's data base, as follows:

Keeping informed

You can be placed on a mailing list for future advice on a specific application or proposal by contacting the Standards Management Officer at standards.management@foodstandards.gov.au and attaching this [completed form \(word 101 kb\)](#).

You can also register online to read about applications and proposals FSANZ is developing by registering to our [subscription service](#). For assistance in registering online contact the FSANZ Information Officer in Australia email information@foodstandards.gov.au

If you have any specific clarifications or require further information, please contact the Project Manager, Dr Glenn Stanley or (02) 62712643 or glenn.stanley@foodstandards.gov.au.

Attachment 5 – Consultation with stakeholders in November 2013

In November 2013, a questionnaire was sent out to 46 raw apricot kernel businesses (importers, producers and retailers) in both Australia and New Zealand. Businesses were identified by online research and from customs import data. Please see a copy of the questionnaire sent to apricot kernel businesses below.

FSANZ received eight responses, all from Australia. Two businesses indicated that they no longer imported raw apricot kernels. One business only imported apricot kernel oil. One importer indicated that they would provide some information, but to date no response has been received. Four other businesses provided their import/production numbers, costs and other information.

Of the four businesses that provided import/production numbers³⁵, all four reported importing raw apricot kernels, and one of the four also reported producing raw apricot kernels. Two of the businesses imported only skin off apricot kernels and the other two only skin on apricot kernels. The volumes the businesses reported importing ranged from 450 to 7,000 kg of skin on apricot kernels for about \$5–7 per kilogram and from 100 to 500 kg of skin off apricot kernels. The company which produced apricot kernels reported producing 9,000–12,000 kg per year of dried skin on apricot kernels for around \$9.50 per kilogram.

All four businesses were wholesalers (selling to retailers). The number of retail businesses they reported supplying ranged from six to 3,000 retail businesses. Two of the four businesses also sold raw apricot kernels directly to the public.

³⁵ This does not include the business that only imported apricot kernel oil.

Questions sent to targeted stakeholders in 2013

a) Questions for apricot kernel importers

If your business is based in Australia we will assume your answers to the following questions are in Australian dollars. If it is based in New Zealand we will assume answers are in New Zealand dollars. If it is in both countries please provide answers in Australian dollars.

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³⁶ For example (amaretti biscuits, almond finger biscuits, apricot jams, apricot nectar)
³⁷ For example (apricot kernel oil, amaretti biscuits, almond finger biscuits, apricot jams, apricot nectar)

b) Questions for domestic apricot kernel producers

If your business is based in Australia we will assume your answers to the following questions are in Australian dollars. If it is based in New Zealand we will assume answers are in New Zealand dollars. If it is in both countries please provide answers in Australian dollars.

In which country is your business based? Write Y in the box next to the country(ies) in which

³⁸ For example, (amaretti biscuits, almond finger biscuits, apricot jams, apricot nectar)

Attachment 6 – Consultation with stakeholders 2014–15

From December 2014 to February 2015 further consultation was also undertaken with stone fruit manufacturers, Horticulture Australia Horticulture New Zealand, canning and dried fruit manufacturers as part of the process of developing the evidence base for the decision RIS.

FSANZ contacted stone fruit, canning and dried fruit manufacturers to check if the Proposal would have any impact of those business (e.g. if they supply discarded apricot kernels to other businesses). No impact on the business contacted was identified.

The Call for Submissions and the Consultation RIS (Supporting Document 2 to the Call for Submissions) were made available for public comment from 16 December 2014 to 10 February 2015³⁹. Questionnaires for industry (Attachment 4 of this report) and consumers (available below) were included in the Consultation RIS.

FSANZ did not receive any submissions from industry. FSANZ did receive twelve private submissions, but none of the private submitters completed the questionnaire for consumers (available below).

Also, further consultation was undertaken with government agencies to discuss issues raised by jurisdictions and by China (as part of the WTO notification) during the public consultation period. This work has informed the development of the draft variation to the Australia New Zealand Food Standards Code.

Questions for consumers from the Consultation RIS (Attachment 4 to the Consultation Regulation Impact Statement)

Apricot kernels are nut-like seeds found in the stone of fresh apricots. They can be bought with the skin on (unhulled) or with the skin off (hulled). Some processed foods, such as amaretti biscuits and apricot jam can include apricot kernels as an ingredient.



Raw skin on (unhulled) apricot kernels



Raw skin off (hulled) apricot kernels

³⁹ The Call for Submissions and its supporting documents (including the Consultation RIS) are available from the [FSANZ website](#).

Question 1. Have you ever bought dried apricot kernels...? Please tick all that apply.

- A On their own (e.g. a bag of dried apricot kernels)
- B As part of a soup mix?
- C In a food in which they're used as an ingredient (e.g. biscuits, apricot jam)?
- D As apricot kernel oil?
- E In some other form. Please specify

If you did not tick 'On their own' (Box A above) please do not complete any further questions in this survey. At this stage, FSANZ is interested only in consumers purchasing or consuming apricot kernels on their own. Thank you for your time.

If you did tick 'On their own' please go to Question 2.

Question 2. When you have bought apricot kernels on their own (e.g. a bag of dried apricot kernels), which of the following types have you bought? Please tick all that apply.

- Kernels with skin on (unhulled)
- Kernels with skin off (hulled)

Question 3. If apricot kernels with skin on (unhulled) are unavailable would you switch to buying apricot kernels without skin (hulled) if they were available?

- Yes
- No

Question 4. Thinking about all of the times you have bought apricot kernels, which of the following have you used them for? Please tick all that apply

- A To prepare a particular food (e.g. biscuits, apricot jam) in which the kernels are cooked
- B To prepare something other than food (e.g. a body scrub)
- C To eat for health reasons

If you did not tick 'To eat for health reasons' (Box C above) please do not complete any further questions in this survey. At this stage, FSANZ is interested only in consumers purchasing or consuming apricot kernels to eat for health reasons. Thank you for your time.

If you answered 'To eat for health reasons' (Box C above), please answer Question 4, below.

Question 5. When you eat apricot kernels, how do you usually prepare them?

- A I usually eat them raw (uncooked) and whole
- B I usually eat them raw (uncooked) and crushed
- C I usually cook them

Question 6. Which of the following health effects (if any) are you hoping to achieve by consuming apricot kernels?

- A I'm not trying to achieve any health benefits from consuming apricot kernels
- B I don't currently have cancer, but I am trying to reduce my risk of developing it (i.e. cancer prevention)
- C I currently have cancer, and am trying to treat the cancer
- D I am trying to strengthen my immune system
- E I am trying to manage arthritis pain
- F I am trying to lower my blood pressure
- G I am hoping to achieve some other health effect. Please specify

Apricot kernels contain hydrocyanic acid, and so can cause cyanide poisoning when consumed. Processing apricot kernels (for example by cooking them) reduces the cyanide to safe levels. So products, such as biscuits, jams, etc. do not pose a risk to consumers.

Please see the Food Standards Australia New Zealand website if you would like further information on the risks of consuming raw apricot kernels:

<http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx>

Question 7. Were you aware, before reading this survey, that eating raw apricot kernels can cause cyanide poisoning?

Yes

No

Attachment 7 – Summary of submissions and FSANZ response

FSANZ called for public comment from 16 December 2014 to 10 February 2015 after assessing the Proposal.

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on the Proposal was considered and reviewed by FSANZ staff, who examined the issues identified and prepared a response (see Table 9, below). All comments are valued and contribute to the rigour of our assessment.

Table 9 Summary of issues (from the Approval report)

| Issue | Raised by | FSANZ response |
|---|--|---|
| Supports the prohibition with exemptions for apricot-kernel derived foods that are safe for consumption. | Food Technology Association of Australia | |
| Support prohibition approach as concerned that two family members consumed apricot kernels as a cancer treatment rather than continuing with treatment prescribed by a medical practitioner. The legislation should go further to regulate the alternative therapy practitioners that are profiting from people who are being killed by such treatments. | Jo Maddren | FSANZ notes this submission and agrees that there is no evidence that consumption of apricot kernels can cure cancer (see below submission from the Cancer Council). |
| <p>Cancer Council strongly welcomes and supports a regulatory approach (prohibition on the sale of both unhulled (skin on) and hulled (skin off) raw apricot kernels in Standard 1.4.4 with exemptions for raw apricot kernel-derived foods that are safe for consumption (option 5 presented in the call for submissions). Our organisation supports the view of FSANZ that this is likely to have the greatest net benefit in managing the risk to public health and safety from consumption of raw apricot kernels.</p> <p>More recently, in addition to the two cases of poisoning reported in Australia, the Department of Health in Hong Kong issued a warning against consuming raw apricot seeds due to a case of</p> | Cancer Council | <p>FSANZ notes the submission from the Cancer Council that there is no evidence that available scientific evidence does not support consumption of apricot kernels as a cancer treatment.</p> <p>In addition, that some raw apricot kernels are promoted as an alternative therapy for cancer treatment. However the Cancer Council of Australia states that they are not only ineffective at treating cancer but could also be very dangerous.</p> |

| Issue | Raised by | FSANZ response |
|--|---------------|--|
| <p>poisoning in a 26 year old male.</p> <p>The continuing sale of apricot kernels as health food is of major concern given the risk of poisoning and death. There is no evidence that the consumption of apricot seeds related to the use of laetrile is effective in the treatment or prevention of cancer.</p> <p>The consensus of available scientific evidence does not support claims that laetrile is an effective anti-cancer treatment either in animal studies or in human clinical trials. Given the lack of scientific evidence for the use of raw apricot kernels for cancer treatment as well as the risk to public health, the Cancer Council strongly welcomes and supports the prohibition on the sale of raw apricot kernels.</p> | | |
| <p>Welcome FSANZ’s regulatory approach and strongly support the prohibition of the sale of unhulled and hulled raw apricot kernels under Standard 1.4.4 with exemptions for apricot kernel-derived foods that are safe for consumption (option 5 in the proposal). This position has been taken because of the public health risk posed by the sale of apricot kernels, particularly to vulnerable consumers.</p> <p>Presented the view that vulnerable consumers are most affected by current arrangements and businesses selling apricot kernels are taking advantage of people who are sick and looking for hope. A ban is needed to prevent businesses profiting from the spread of misinformation and the sale of a dangerous good.</p> | CHOICE | FSANZ notes and agrees with this submission. |
| <p>Support the status quo, with no additional government actions whatsoever except continued provision of information on safe limits for consumption. People should be allowed choices in regard to what they consume or how they choose to be treated or not treated for disease.</p> | Kathleen Swan | <p>FSANZ notes the submission.</p> <p>FSANZ always uses the best available science in consideration of any risk management options.</p> <p>FSANZ has identified a significant acute public health and safety dietary</p> |

| Issue | Raised by | FSANZ response |
|--|---|---|
| <p>Requested that the prohibition be rejected as people may seek alternative treatments after conventional has failed. There still needs to be a way in which researchers can access amygdalin for testing.</p> | <p>Brian Sandle</p> | <p>risk from exposure to HCN from consumption of raw apricot kernels and remains concerned that poisoning incidents are still occurring despite voluntary warning statement on some raw apricot kernel packaging.</p> |
| <p>Opposed to the prohibition based on the evidence supporting foods containing dietary cyanides being a valuable therapeutic tool, and the cyanide component is an essential part of the treatment value.</p> | <p>Individual consumer⁴⁰</p> | <p>In summary, the proposal to vary Standard 1.4.4 to prohibit the sale of raw apricot kernels, both unhulled (with skin) and hulled (without skin), was made for the following reasons:</p> |
| <p>Does not support the prohibition on apricot kernels. Outlined reasons why he considered that FSANZ had not followed the requirements in the FSANZ Act, in particular use of the best scientific evidence available. Also criticised that FSANZ based its assessments on Codex principles which exists purely to promote trade, power and profit for multinational corporations.</p> <p>Felt that the public consultation process was inadequate, FSANZ has failed to conduct a meaningful risk analysis taking into account a variety of ingested substances and other causes of death and harm and that there is no independent peer review of FSANZ's proposal in accordance with good scientific principles.</p> | <p>Individual consumer</p> | <ul style="list-style-type: none"> • it lowers the risk of future poisoning from consumption of raw apricot kernels that may contain high levels of HCN and supports the primary objective of protecting public health and safety • it protects new consumers unaware of risks of consumption of raw apricot kernels and from the unproven health benefit claims associated with the sale of some apricot kernels, supporting the objective of prevention of misleading or deceptive conduct. |
| <p>Oppose the proposal to ban apricot kernels from sale in New Zealand.</p> <p>Urged FSANZ to consider labelling of apricot kernels directing people to seek professional advice prior to consumption due to a risk of poisoning if wrongly prepared or consumed in excessive quantities rather than ban this traditional anticancer food.</p> | <p>Katherine Smith</p> | |
| <p>Support no change as believes that consumers have the right to make their own decisions about what they eat.</p> | <p>Jane Gale Cory Guly</p> | |

⁴⁰ Individual consumers did not give FSANZ permission to release their names

| Issue | Raised by | FSANZ response |
|---|--|---|
| <p>Suggested that the CFS Report contains a lot of scientific evidence about the theoretical dangers of cyanide poisoning from apricot kernels but very little actual, real life evidence.</p> <p>Supports option 1 (status quo) with option 2 (labelling) as a second preference, although it may penalise manufacturers, retailers or consumers.</p> | <p>Deb Gully</p> | |
| <p>Stated that members of her family consumed apricot kernels without any adverse effects and that the prohibition would just restrict and deny people choosing a healthy diet.</p> <p>Presented data in animals where HCN (hydrogen cyanide) was administered and showed no adverse effects.</p> | <p>Heather Howard</p> | |
| <p>Opposed to the prohibition as there is evidence that foods containing dietary cyanides are a valuable therapeutic tool.</p> | <p>Ian Gregson</p> | |
| <p>Disagreed with the proposed prohibition of apricot kernels. FSANZ should look at the science because if apricot kernels did not control cancer then consumers would not buy them.</p> | <p>Bill Leonard</p> | |
| <p>Suggests that people should take responsibility for their own choices rather than FSANZ ban foods.</p> | <p>Julie Noakes</p> | |
| <p>The Almond Board of Australia Raised an issue with FSANZ in regard to a reference in the Call for Submissions Report that the concentration of HCN in bitter almonds and apricots can reach toxic levels. They requested that FSANZ revise the text when referring to bitter almonds to note that almonds produced and consumed in Australia were sweet almonds containing no cyanogenic compounds.</p> <p>This was supported by a submission from Nuts for Life, who requested that in any consumer materials, web copy and reports on this issue that statements are included that “sweet” almonds are safe to eat and are</p> | <p>Almond board of Australia and Nuts for Life</p> | <p>FSANZ has amended the text in the Approval Report to reflect that almonds produced and consumed in Australia are sweet almonds, contain low levels of HCN and are safe to eat.</p> |

| Issue | Raised by | FSANZ response |
|---|--------------------|---|
| different from “bitter” almonds to avoid any further confusion. | | |
| <p>NZFGC opposes a prohibition on the sale of apricot kernels as this appears to be draconian measure and that other options have not been exhausted, in particular mandatory labelling. NZFGC also considers that consumer choice should be preserved in the food supply wherever possible.</p> <p>There was a high focus in the Regulatory Impact Analysis (RIS) on the determination of sellers and buyers to exploit apricot kernels as an alternative medicine which is beyond the scope of the food control system.</p> <p>Suggested that labelling advice could be more generic than recommending a number of kernels that might be consumed.</p> <p>For example:</p> <p>“There are identified acute dietary risks and potentially severe acute potential poisoning associated with the consumption of raw apricot kernels. The product is not suitable for children and adults should be cautious in consuming kernels because of variable levels of the substance they contain that results in cyanide poisoning.”</p> <p>Recommends that mandatory labelling be applied for a given period, (e.g. 5 years) followed by an evaluation of the effectiveness of the measure.</p> | NZFGC | <p>FSANZ has undertaken a Consultation RIS based on the available information which was approved by the OBPR.</p> <p>Acute dietary risks were identified following consumption of apricot kernels, there is a continuation of reports of poisoning (e.g. recently in WA) and consumer advice or labelling does not appear to be an adequate measure.</p> <p>Labelling was not considered appropriate because:</p> <ul style="list-style-type: none"> • poisoning incidents continue despite the voluntary advice on the labels on packages • labelling may not effectively manage a potentially serious public health risk for the general community, as it depends on consumers reading and acting on the information • the variability in the HCN levels and in particular maximum limits of HCN means that, it is difficult to predict a safe number of kernels that could be consumed per day. This would make it impractical to determine a labelling statement that would be adequate to address the acute public health implications for all potential consumers. Furthermore, any advice on maximum consumption could become out-of-date as more information on the maximum levels which may occur becomes available • the general availability of raw apricot kernels, including for children (which is the group at greatest risk of exceeding safe doses) means that it would be inadequate to rely on specific labelling statements to protect public health and safety • the most recent poisoning incident occurred in Western Australia despite the presence of clear warning labels on the packaging and website from which product was purchased. |
| <p>Supports Option 5 to prohibit the sale of raw apricot kernels for the protection of public safety due to the high toxicity of these products, especially for children. Raised the following specific issues:</p> | NSW Food Authority | <p>FSANZ understands that blanched apricot kernels are obtained by boiling raw apricot kernels (with skin on) at high temperatures resulting in a skinless, pale coloured kernel. Therefore, FSANZ considers that blanching would be considered a hulled (skin-off) apricot kernel.</p> |

| Issue | Raised by | FSANZ response |
|---|-------------------------------------|---|
| <p>(i) Prescribing a list of acceptable products requires some guidance to industry and consumers as to when a food that contains or is made using apricot kernels is safe for human consumption. An example of this is blanched apricot kernels. Recent testing of blanched apricot kernels by the NSW FA resulted in levels of total cyanide ranging from 32 to 90 mg/kg which were lower than raw apricot kernels. Questioned what would be the status of a blanched product?</p> <p>(ii) Unclear whether an unintended consequence from a prohibition would result in this product being supplied to consumers through markets where it is purposely represented as a cosmetic product; or a therapeutic good to avoid the ban as a food.</p> <p>(iii) The proposal does not consider that, to be effective, any prohibition of raw apricot kernels may need to be implemented across a number of government portfolios with broader strategies that: (a) prevents raw apricot kernels being misrepresented as for use as a cosmetic; and (b) prevents therapeutic claims being made either directly or indirectly with the sale of raw apricot kernel products.</p> <p>A risk communication strategy should be developed and implemented in conjunction with public health groups and the medical profession to assist with reaching those more at risk.</p> | | <p>FSANZ notes the range of HCN levels in the survey undertaken by the NSWFA in comparison with levels found in the ISFR survey 49 to 440 mg/kg (10 individual samples).</p> <p>FSANZ has moved to address risks from dietary exposure to apricot kernels and has no powers under the FSANZ Act to consider non-food uses or claims of a therapeutic nature either made directly or indirectly (this is a matter for the Therapeutic Goods Administration). FSANZ has recently approached both the Australian Competition and Consumer Commission (ACCC) and Commerce Commission New Zealand (NZCC) seeking advice on what action they may take against the sale of raw apricot kernels via the internet in regard to misleading claims even if a prohibition was in place under the prohibited botanicals standard. Refer to section 2.3.1.1 for more discussion on this issue.</p> <p>FSANZ notes the suggestion that for effective prohibition this may need to be implemented across a number of government portfolios, similar to the process employed for the recent bath milk incident. Specifically, around a national approach to the issue via engagement with consumer affairs Ministers. FSANZ has approached ISFR to facilitate future discussion on this issue.</p> <p>A FSANZ communication plan has been developed. The Approval report will be included in the Food Standards Notification Circular and supported by a media release; social media; stories in publications and email notifications.</p> <p>FSANZ's key messages were:</p> <ul style="list-style-type: none"> • FSANZ is taking action to ensure consumers are protected • FSANZ has put in place a food regulatory measure to address the risks of poisoning from eating apricot kernels • this action is backed by a rigorous safety assessment process • FSANZ has consulted on the impacts on industry on this regulatory measure. |
| <p>Support the prohibition with exemptions for apricot kernel-derived foods that are safe for consumption.</p> | <p>The Victorian Departments of</p> | <p>FSANZ notes and welcomes the suggestion of a more strategic consideration regarding how non-food raw apricots kernels may be sold</p> |

| Issue | Raised by | FSANZ response |
|--|--|---|
| <p>However, have some concerns that the variation, as drafted, will impact on legitimate use of these products:</p> <p>(i) non-food uses: some businesses will sell a food under the guise of a non-food product, as has been seen with raw milk sold as bath milk. This will create enforcement issues for regulatory agencies. It is our view that there needs to be a more strategic consideration regarding how non-food raw apricots kernels may be sold to consumers.</p> <p>(ii) As poisoning incidents are relatively uncommon, and no information is provided on severity, prohibition may not address all opportunities to purchase these products, nor prevent people from consuming the kernels, would support a more detailed impact analysis for each of the risk management options provided, including the possibility of clearer labelling advice for these products and specifying processing requirements.</p> <p>(iii) the wording of the draft variation needs amendment, with further clarification as to the basis of the exemptions included to allay any concerns about the safety of exempted products. It is noted that the exemption list is not exhaustive, and has excluded foods such as apricot jams, persipan or blanched kernels without any apparent reason. However, an exclusion list may cause problems for enforcement agencies in the future, as new products or existing products that contain raw apricot kernels that are not listed may be</p> | <p>Health and Human Services and Economic Development, Jobs, Transport and Resources (the Departments)</p> | <p>to consumers.</p> <p>FSANZ undertook a robust RIS which was agreed by OBPR. There was consideration of all options, a targeted consultation with industry and food enforcement agencies in 2012 and 2013 as well as the analysis of the impacts of each option.</p> <p>FSANZ does not consider labelling as an appropriate option to mitigate acute dietary risks from apricot kernels and is unaware that kernels can be further processed to reduce HCN to safe levels. Even with hulled kernels an acute dietary risk remains.</p> <p>FSANZ has amended the drafting to address these issues. See section 2.3.2</p> |

| Issue | Raised by | FSANZ response |
|---|--------------------|--|
| <p>potentially in breach of the variation, although they do not present a public health risk. This may hinder industry innovation, discouraging new food product development unless a business is willing to make an application to amend the Code. This can be prohibitively expensive for small to medium size enterprises.</p> <p>It is the Departments' view that the draft variation should be less specific, worded in such a way that raw apricot kernels are only allowed to be added as an ingredient of food if processing will take place to reduce any risk associated with the consumption of the final food. This may include the removal of the cyanogenic glycosides via an appropriate process. Taking this approach, specifying processing of the kernels so they are safe to consume (for example as stone fruit juices or confectionary) would also be consistent with the requirements for sweet cassava and bamboo shoots that exist in the Code. The adoption of the alternative wording would reduce the potential impacts on the supply of raw apricot kernels to other manufacturers.</p> | | |
| <p>Indicated that the issue of HCN in apricot kernels was raised by NSW at the FSANZ chaired Technical Advisory Group (TAG) in April 2004. FSANZ made various undertakings and TAG agreed to postpone discussion until the relevant information from FSANZ was available.</p> <p>Raised a number of issues in regard to the drafting: What constitutes "raw"? It may be that mildly blanched kernels are arguably not raw; however, the HCN content may still be of concern. Suggested that a maximum limit would offer better protection of public health and safety in raw kernels or otherwise.</p> | <p>Bill Porter</p> | <p>FSANZ has defined raw as the following:</p> <p><i>The term 'raw apricot kernel' refers to the edible nut-like object found within the shell or stone of Prunus armeniaca either unhulled (with skin) or hulled (without skin).</i></p> <p>FSANZ is proposing that the prohibition would apply to hulled apricot kernels and understands that blanching can result in unhulled varieties. FSANZ is concerned that hulled apricot kernels also pose an acute dietary risk, and that similar to unhulled varieties there is a large variability in HCN (in particular maximum) levels.</p> <p>It was not the intent of subclause 3 to allow the sale of sugar coated raw</p> |

| Issue | Raised by | FSANZ response |
|---|-----------|---|
| <p>Subclause 3 of the drafting appears to allow the sale of confectionery in the form of sugar coated raw apricot kernels, and also allow any substance derived from raw kernels (including an extract high in HCN which are contrary to the apparent intent of the variation.</p> | | <p>apricot kernels but rather confectionary that used small amounts of apricot kernels as ingredients that are safe for consumption. This exclusion for confectionary is also supported by an ML of 25 mg/kg for confectionary in Standard 1.4.1 (or schedule 19 of the revised Code) Contaminants and Natural Toxicants.</p> <p>FSANZ has amended the drafting to include a cross reference to Standard 1.4.1 Contaminants and Natural Toxicants (and Schedule 19 of the revised Code) which lists MLs for HCN in confectionary, stone fruit juices, marzipan and alcoholic beverages. The ML for confectionary addresses the issue of sugar/chocolate coating of apricot kernels.</p> |

| Issue | Raised by | FSANZ response |
|---|--------------|---|
| <p>Supports the prohibition on sale of unhulled (skin on) and hulled (skin off) apricot kernels. Concerned that the level of variation in HCN in kernels creates challenges in developing and administering risk management strategies such as labelling or consumer advice.</p> <p>Concerned that the draft variation may still allow the addition of raw apricot kernels to foods such as cakes, biscuits and confectionary. For example, chocolate covered apricot kernels (sold as confectionary), or ground up apricot kernels added to a muesli bar (sold as a cake or biscuit). MPI proposes that this might be avoided by an ML in Standard 1.4.1 Contaminants and Natural Toxicants for cakes, biscuits, oils and confectionary.</p> <p>Provided the following information to FSANZ:</p> <p>Medsafe (under the Ministry of Health) has indicated that they would not regard apricot kernels as a dietary supplement (given they are presented more like a food)</p> <p>If the proposed draft variation was accepted, the New Zealand Supplemented Food Standards (2013) would not permit apricot kernels by virtue of the prohibition under Standard 1.4.4 Prohibited Plants and Fungi.</p> <p>New Zealand Customs data indicated that between 2011 and 2013 there was an average of 264 kg imported; in 2014, 1280 kg were imported, the increase due to a single shipment from Turkey of 1000kg. Import data showed that end use is likely to be raw consumption rather than further processing.</p> <p>MPI has been unable to obtain information from the industry on the manufacture and sale of apricot kernels in New Zealand. No food type dietary supplements were identified as containing apricot kernels. MPI identified 7 unique cake and biscuit products containing apricot kernels as an ingredient during 2013-14 similar to that identified in FSANZ's assessment.</p> | <p>NZMPI</p> | <p>It was not the intent of subclause 3 to allow the sale of chocolate coated raw apricot kernels but rather confectionary that used small amounts of apricot kernels as ingredients from which the final product was safe for consumption. An example is persipan, a confectionary which is similar to marzipan but apricot kernels are used instead of almonds. The exclusion for confectionary is also supported by an existing ML of 25 mg/kg for confectionary in Standard 1.4.1 Contaminants and Natural Toxicants. Therefore, if a business moved to either sugar or chocolate coat an apricot kernel to avoid the prohibition, the existing ML for confectionary would still need to be met.</p> <p>In respect of ground up apricot kernels added to a muesli bar (sold as a cake or biscuit) various foods containing apricot kernels as ingredients were analysed for the presence of HCN in the ISFR survey (amaretti biscuits and almond finger biscuits) and were found to not pose a public health and safety risk.</p> <p>Levels of HCN in apricot oil were not measured in the ISFR survey. However, it is considered there is no potential HCN poisoning risk associated with its consumption. Amygdalin (the cyanogenic glycoside in apricot kernels) is hydrophilic and does not readily partition into oil. Therefore, the HCN levels in the final oil product are anticipated to show a similar reduction in HCN levels to that seen for linseed when processed to linseed oil (main cyanogenic glycoside being linustatin). A study by Viorica-Mirelaet et al. (2006) was unable to detect amygdalin in apricot kernel oil.</p> <p>Furthermore, FSANZ is not aware of any clinical cases relating to apricot kernel oil consumption with adverse effects in humans. Administration of apricot kernel oil via the diet (10% w/w) to laboratory rats for 90 days showed no adverse effects (Gandhi et al 1997). In the United States (US), the US Food and Drug Administration (FDA) has assigned a GRAS status (Generally Regarded as Safe) to apricot kernel (persic) oil (USFDA).</p> <p>Therefore, FSANZ did not see a specific need to establish MLs for cakes, biscuits, oils or confectionary, due to no identified public health and safety concerns, noting that there is an existing ML for confectionary in Standard 1.4.1. (and Schedule 19 of the revised Code). However, in order to fully address these issues, FSANZ will prepare guidance material for jurisdictions to assist in future enforcement activities.</p> |

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| <p>Raised an issue in regard to whether the options had considered the sale of raw apricot kernel skin (as it is high in laetrile) although it is noted that the draft variation includes raw apricot kernels or any substance derived there from.</p> <p>The Call for Submissions and the supporting documents do not discuss the risks associated with cooked apricot kernels or provide any information in relation to the published cases referred to of cyanide poisoning from eating cooked apricot kernels. An issue to consider could include whether light roasting of apricot kernels makes them safe to consume. If there is a risk from eating cooked or partly cooked apricot kernels then consideration should be given to prescribing a maximum limit for hydrocyanic acid in heat treated apricot kernels.</p> <p>If the recommended regulatory measure is accepted and the sale of raw hulled and unhulled apricot kernels is prohibited (with the exceptions noted in the FSANZ Call for Submissions paper), it will still be possible for consumers to purchase fresh whole apricots to obtain raw apricot kernels. As such, consideration would need to be given to maintaining some authoritative information for the public on the FSANZ or Commonwealth Department of Health website warning of the dangers of consuming apricot kernels.</p> | <p>Food Safety Standards and Regulation Health Protection Unit Department of Health Queensland Government</p> | <p>FSANZ understands that the majority of kernels are being sold with skin on due to the purported health benefits. Recent advice is that the majority of HCN is contained in the apricot kernel pulp and not in the skin suggesting that there are no public health and safety concerns from the skin.</p> <p>FSANZ has proposed in the Call for Submissions Report that an ML would not serve as an effective mitigation measure for HCN in raw apricot kernels, which would include heat-treated kernels because of the variability in levels of HCN in apricot kernels.</p> <p>However, the amended drafting in section 2.3.2 addresses the issue of a treatment or processing step (such as heating) being applied to render the final food safe for human consumption.</p> <p>FSANZ will maintain the current website advice.</p> |

Attachment 8 - World Trade Organisation

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to prohibit the sale of raw apricot kernels, both with skin and without skin and any substance derived from raw apricot kernels which is not processed further may have a significant effect on international trade. The majority of apricot kernels used in Australia (approximately 20,000 kg per annum worth approximately \$600,000 to the apricot kernel industry) is imported. The targeted consultation undertaken with apricot kernel businesses in New Zealand did not provide any feedback on the use of this product in New Zealand. However, it is expected that, similarly to Australia, the majority of the kernels used there are imported. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary Measures Agreement was made to enable other WTO members to comment on the proposed amendments.

Comments from one World Trade Organization (WTO) member (China) was received which raised the following issues:

- Considered that it was unreasonable to prohibit the sale of raw apricot kernels because: (i) they contain various nutrients (vitamin E, monounsaturated fat and dietary fibre) which may reduce heart disease; and (ii) prohibition may influence international trade
- As the basis of the prohibition is a qualitative evaluation, FSANZ should as a transitional measure undertake a quantitative approach and set MLs
- FSANZ should strengthen enforcement of misleading claims associated with apricot kernels
- Because apricot kernels consist of both sweet and bitter varieties, suggested that FSANZ should undertake a classification and risk assessment of both varieties and then on this classification basis set maximum limits (MLs) for HCN.

FSANZ is preparing a response to the WTO.