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[24–15]

Approval Report – Proposal P1016

Hydrocyanic Acid in Apricot Kernels & other Foods

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared for the risk management of hydrocyanic acid in apricot kernels and other foods.

On 16 December 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received twenty three submissions.

FSANZ approved the draft variations on 17 September 2015. The Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 1 October 2015.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting document

The following document which informed the assessment of this Proposal is available on the FSANZ website at

<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1016hydrocy5438.aspx>:

SD1 Poisoning incidents from hydrocyanic acid in apricot kernels and regulation of HCN in general foods in other countries (at Approval)

Executive summary

Some plant-based foods, such as cassava and apricot kernels, contain cyanogenic glycosides which may pose a health risk to consumers. The toxicity of cyanogenic glycosides in humans and animals arises because they are converted by gut bacteria to hydrocyanic acid (HCN). If sufficient cyanogenic glycosides are consumed, then cyanide poisoning may follow.

As a result of a previous proposal addressing the levels of HCN in ready-to-eat cassava chips, FSANZ recognised that a more thorough review of cyanogenic glycosides should be done to determine whether there are any public health and safety concerns in a range of other foods. The levels of HCN in foods were assessed in a coordinated food survey under the Implementation Subcommittee for Food Regulation's (ISFR's) Coordinated Food Survey Plan.

This Proposal was prepared to consider either non-regulatory or regulatory measures to manage public health or safety issues identified as a result of the ISFR survey. After analysing the survey results and undertaking a risk assessment FSANZ determined there were no public health and safety concerns for foods other than raw apricot kernels. FSANZ's risk assessment indicated that consumption of raw apricot kernels, both unhulled (with skin) and hulled (without skin), poses an acute public health and safety risk for consumers.

There have been reports of poisoning in Australia, New Zealand and other countries (Canada, USA, United Kingdom, Hong Kong and Europe) following consumption of raw apricot kernels. In May 2011 and July 2014, single consumers in Queensland and Western Australia, respectively, were hospitalised after consuming raw apricot kernels with high levels of HCN.

FSANZ released a call for submissions on proposed draft variations to the Code in December 2014. Twenty-three submissions were received and issues raised have been addressed in this Report. The Regulatory Impact Statement could not make a clear recommendation for a non-regulatory or regulatory intervention because of uncertainties in relation to industry costs and the quantification of the harm likely to be avoided.

The FSANZ Board has approved draft variations to the current Code and to the revised Code to prohibit the retail sale of raw apricot kernels to consumers and to require kernels that are to be added to food as an ingredient to be rendered safe through processing or treatment. This measure was considered warranted given the evidence which identified a risk to public health and safety. It was also considered the most effective in addressing that risk.

1 Introduction

Some plant-based foods, such as cassava and 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.

Many plants store cyanogenic precursors in their seeds. Examples are apples, pears, almonds, apricot, peach, flax and lima beans. The concentration of HCN in seeds varies widely. Almonds and almond products consumed in Australia are sweet almonds, which contain low levels of HCN and are safe to eat. However, in apricots it can reach toxic levels (Haque and Bradbury, 2002; Codex Committee on Contaminants in Foods, 2008).

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's) 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 foods².

The survey identified a small number of foods (raw apricot kernels, cassava roots and bread containing linseed) for which the acute dietary exposure had the potential to exceed the acute reference dose (ARfD)³. Of these foods, the consumption of raw apricot kernels both with and without skin poses the greatest acute public health and safety risk for Australians and New Zealanders. No specific risk management measures were required for cassava roots or bread containing linseed based on the risk assessment findings (see 2.2 below).

During the 1970s and 80s, amygdalin (also known as laetrile or 'Vitamin B17', although it is not a recognised vitamin) was extracted from apricot kernels and sold as a treatment for cancer. The efficacy of the treatment was never proven and it was associated with significant toxicity. The practice of marketing apricot kernels as a cancer treatment continues today.

In May 2011, a consumer in Queensland was hospitalised after consuming raw apricot kernels with high levels of HCN. In October 2011, the National Food Incident Protocol was triggered to alert all jurisdictions to this incident. The likelihood of someone else becoming ill from eating these foods was considered high and on 4 November 2011, FSANZ issued a statement alerting the public against consuming raw apricot kernels⁴. At the time of the poisoning incident in Queensland, there were a number of voluntary recalls and further investigations by state, territory and New Zealand jurisdictions.

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 Western Australia poisoning incident resulted in a FSANZ-initiated national product recall.

Poisoning incidents following either accidental (children and adults) or intentional ingestion (by adults only) of raw apricot kernels in Australia and New Zealand have been reported to poison information centres. This information is summarised in Attachment D.

² <http://www.foodstandards.gov.au/publications/Pages/Report-on-survey-of-cyanogenic-glycosides-in-plant-based-foods.aspx>

³ An estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer.

⁴ <http://www.foodstandards.gov.au/media/Pages/mediareleases/mediareleases2011/fsanzwarnsaagainstcon5338.aspx>

Poisoning incidents from consumption of apricot kernels have also been reported in other countries: Canada, USA, Hong Kong, United Kingdom and Europe (see SD1). In countries other than Australia and New Zealand, the risk of poisoning incidents has been managed by:

- Prohibition on the sale of apricot kernels as a food since they are regulated as a drug (laetrile (amygdalin)) under import legislation (USA).
- Regulation of apricot kernels with very high HCN levels, under general Food Safety Acts, which makes it an offence to sell or possess for sale food which is injurious to health (Europe)⁵.
- Advice for consumers on a recommended maximum number of apricot kernels to be consumed per day (United Kingdom and Canada).

1.1 The Proposal

FSANZ prepared this Proposal to:

- consider the potential public health and safety risks associated with consuming raw apricot kernels and food products and substances derived from raw apricot kernels; and if needed, other HCN-containing foods, that may have public health and safety risks as based on the findings from the recent ISFR survey on cyanogenic glycosides in food.
- develop appropriate risk management strategies to manage these risks, including consideration of a need for food regulatory measures in the Code.

FSANZ considers raw apricot kernels to be a food and does not address the issue of these foods being consumed for a therapeutic purpose or presented as a therapeutic good. FSANZ considers that the classification and use of these products as a therapeutic good is outside the scope of a food regulatory matter.

Throughout this assessment summary, the term 'raw apricot kernel' refers to the nut-like object found within the shell or stone of *Prunus armeniaca* either unhulled (with skin) or hulled (without skin). Hulled, apricot kernels are usually pale white in colour⁶.



Unhulled (with skin)



Hulled (without skin)

⁵ Between 2005 and 2008, 15 notifications on cyanide in apricot kernels were transmitted through the Rapid Alert System for Food Feed (RASFF) database of the European Commission. The levels reported range between approximately 300-2500 mg/kg.

⁶ <http://www.hc-sc.gc.ca/fn-an/pubs/securit/2009-apricots-abricots/index-eng.php>.

1.2 The current Standard

1.2.1 Hydrocyanic acid in apricot kernels

There is currently no standard in the Code for HCN levels in raw apricot kernels. Foods containing cyanogenic glycosides are controlled in the Code by a range of measures - maximum levels (MLs) for specific foods, directions for use and preparation instructions and a prohibition on the sale of cassava with HCN levels greater than a certain level.

FSANZ has completed a review of the Code undertaken under Proposal P1025⁷ in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal on 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. References to both versions will be made throughout this Report as draft variations to both versions have been approved.

Standard 1.4.1– Contaminants and Natural Toxicants sets out the MLs of specified metal and non-metal contaminants and natural toxicants in nominated foods. Standard 1.4.1 is replicated in the revised Code. The relevant Schedule in that version of the Code is Schedule 19⁸.

Standard 1.4.1 and Schedule 19 include the following MLs for HCN in the following foods:

- 25 mg/kg in confectionery
- 5 mg/kg in stone fruit juices
- 50 mg/kg in marzipan
- 1 mg/kg per 1% alcohol in alcoholic beverages.

There is also an ML of 10 mg/kg for HCN in ready-to-eat cassava chips.

Standard 1.4.4 – Prohibited and Restricted Plants and Fungi lists the species of plants and fungi that must not be added to food or offered for sale as food. Standard 1.4.4 is replicated in the revised Code. The relevant Schedule in that version of the Code is Schedule 23. In Standard 1.4.4 and Schedule 23, there is a prohibition on the sale of cassava other than 'sweet cassava'. Consistent with the existing Codex standard (Codex 2005), sweet cassava is defined in Standard 1.1.2 – Supplementary Definitions for Foods (Standard 1 1 2 – Definitions used throughout the Code, in the revised Code) as 'those varieties of cassava roots grown from *Manihot esculenta Crantz* of the Euphorbiaceae family that contain less than 50 mg per kg of HCN (fresh weight basis)'.

Standard 1.2.6 – Directions for Use and Storage in both the current and revised Code, includes a requirement for raw sweet cassava to be labelled with or accompanied by a statement indicating that sweet cassava should be peeled and fully cooked before being consumed.

Standard 1.2.6 also includes requirements for a statement that indicates that bamboo shoots should be fully cooked before being consumed. There is no specific Schedule in the revised code for Standard 1.2.6.

⁷ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

⁸ <http://www.foodstandards.gov.au/code/Pages/Revised-code-list-of-standards-and-schedules.aspx>

1.2.2 Regulation of HCN in food in other countries

FSANZ has not identified any specific regulatory standards in other countries for HCN in raw apricot kernels. For more information on standards and requirements in other countries for HCN in other general foods, refer to SD1.

1.3 Reasons for preparing Proposal

This Proposal was prepared to consider the risk management of potential public health or safety issues arising from foods assessed as part of an ISFR survey on cyanogenic glycosides on a range of foods and recent poisoning incidents in Australia from consumption of raw apricot kernels.

1.4 Procedure for assessment

The Proposal was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Public submissions were invited on a draft variation which was released for public comment from 16 December 2014 to 10 February 2015.

Twenty-three submissions were received (including a submission from the Chinese Government in response to FSANZ's WTO Notification), with two late comments received after the closing date. Eight of these supported the proposed prohibition with some raising broader issues for consideration by FSANZ and, in addition, comments on the draft variation. Two submitters were non-committal and the remaining 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 good.

In contrast, those opposed to the prohibition considered that apricot kernels have therapeutic value and that FSANZ should not prohibit these foods but leave the responsibility with consumers, the prohibition was too draconian and that generic labelling was more appropriate so as to preserve consumer choice. Submitters' issues are addressed in Table 1.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
<p>Supported the prohibition with exemptions for apricot-kernel derived foods that are safe for consumption.</p>	<p>Food Technology Association of Australia</p>	
<p>Supported 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.</p>	<p>Jo Maddren</p>	<p>FSANZ agrees that there is no evidence that consumption of apricot kernels can cure cancer (see below submission from the Cancer Council Australia).</p>
<p>Strongly supported 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). Supported FSANZ's view that was likely to have the greatest net benefit in managing the risk to public health and safety from consumption of raw apricot kernels.</p> <p>The continuing sale of apricot kernels as health food is of major concern given the risk of poisoning and death. There was 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 was an effective anti-cancer treatment either in animal studies or in human clinical trials.</p>	<p>Cancer Council of Australia</p>	<p>FSANZ notes the submission.</p>

Issue	Raised by	FSANZ response
<p>Welcomed FSANZ’s regulatory approach and strongly supported 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 presented in the call for submissions). This position was taken because of the public health risk posed by the sale of apricot kernels, particularly to vulnerable consumers.</p> <p>Vulnerable consumers were most affected by current arrangements and businesses selling apricot kernels are taking advantage of people who were 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 agrees.
<p>Opposed a prohibition on the sale of apricot kernels and asserted other options had not been exhausted, in particular mandatory labelling. Also considered that consumer choice should be preserved in the food supply wherever possible.</p> <p>There was a high focus in the RIS on the determination of sellers and buyers to exploit apricot kernels as an alternative medicine which was 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><i>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.</i></p> <p>Recommended 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 prepared a Consultation RIS based on the available information. The Decision RIS also addresses consumption by healthy and sick consumers and accidental poisoning.</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. This has resulted in FSANZ recommending a prohibition on the sale of apricot kernels.</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 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

Issue	Raised by	FSANZ response
<p>Supported Option 5 presented in the Call for Submissions report 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> <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 NSWFA 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 did not consider that, to be effective, any prohibition of raw apricot kernels might need to be implemented across a number of government portfolios with broader strategies that: (a) prevented raw apricot kernels being misrepresented as for use as a cosmetic; and (b) prevented 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>NSW Food Authority</p>	<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> <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 addressed the 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 Good Administration). FSANZ has recently approached both the Australian Competition and Consumer Commission (ACCC) and the New Zealand Commerce Commission (NZCC) seeking advice on what action they may take against the sale of these products via the internet in regard to misleading claims even if a prohibition was in place under the prohibited botanicals standard. Refer to section 2.3.7 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 to manage raw milk being sold as bath milk. This may require 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. The communication plan includes consideration of communication and liaison with health professionals and public health groups to help reach those at risk.</p>
<p>Opposed to the prohibition based on the evidence supporting foods containing dietary cyanides being a valuable therapeutic tool, and the cyanide component was an essential part of the treatment value.</p>	<p>Individual consumer⁹</p>	<p>FSANZ is moving to prohibit apricot kernels based on evidence of an acute public health and safety concern. Part of this prohibition protects consumers that may not be aware of the risk of consumption of raw apricot kernels.</p>

⁹ Specific individual consumers did not give FSANZ permission to release their names

Issue	Raised by	FSANZ response
<p>Did not support the prohibition on apricot kernels. 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 existed purely to promote trade, power and profit for multinational corporations.</p> <p>Public consultation process was inadequate, FSANZ 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 was no independent peer review of FSANZ's proposal in accordance with good scientific principles.</p>	Individual consumer	<p>FSANZ relied on the best available science in its risk assessment and in its consideration of any risk management options.</p> <p>After having regard to that evidence, FSANZ has identified a significant acute public health and safety dietary risk from exposure to HCN from consumption of raw apricot kernels. Poisoning incidents are also still occurring despite voluntary warning statement on some products.</p> <p>In summary, the decision to vary Standard 1.4.4 (Schedule 19) to prohibit the sale of raw apricot kernels, both unhulled (with skin) and hulled (without skin), was made for the following reasons:</p>
<p>Opposed 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 the food.</p>	Katherine Smith	<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>Supported no change as consumers have the right to make their own decisions about what they eat.</p>	Jane Gale Cory Guly	<ul style="list-style-type: none"> • FSANZ followed its normal consultation processes, as documented in the consultation section (2.5.1). This provided an opportunity for others to comment on the scientific evidence underpinning the assessment.
<p>Suggested that the assessment summary contained a lot of scientific evidence about the theoretical dangers of cyanide poisoning from apricot kernels, but very little actual, real life evidence.</p> <p>Supported option 1 (status quo) with option 2 (labelling) as a second preference, although it might penalise manufacturers, retailers or consumers.</p>	Deb Gully	<ul style="list-style-type: none"> • See also responses in rows above.
<p>Members of her family consumed apricot kernels without any adverse effects and the prohibition would just restrict and deny people choosing a healthy diet.</p> <p>Presented data in animals where HCN was administered and showed no adverse effects.</p>	Heather Howard	

Issue	Raised by	FSANZ response
Opposed to the prohibition as there was evidence that foods containing dietary cyanides were a valuable therapeutic tool.	Ian Gregson	
Disagreed with the proposed prohibition. FSANZ should look at the science because if apricot kernels did not control cancer, then consumers would not buy them.	Bill Leonard	
Suggested that people should take responsibility for their own choices, rather than FSANZ banning foods.	Julie Noakes	
<p>Issue with a reference in the assessment summary that the concentration of HCN in bitter almonds and apricots could reach toxic levels. 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>Supported by a submission from Nuts for Life, which requested that in any consumer materials, web copy and reports on this issue that statements were included that “sweet” almonds were safe to eat and were different from “bitter” almonds to avoid any further confusion.</p>	Almond Board of Australia and Nuts for Life	FSANZ has amended the text in the this 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>Supported the prohibition with exemptions for apricot kernel-derived foods that are safe for consumption. However, some concerns that the variation would 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 would create enforcement issues for regulatory agencies. There needed to be a more strategic consideration regarding how non-food raw apricots kernels might be sold to consumers.</p> <p>(ii) As poisoning incidents were relatively uncommon, and no information was provided on severity, prohibition might not address all opportunities to purchase these products, nor prevent people from consuming the kernels.</p>	The Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the Departments)	<p>FSANZ notes and welcomes the suggestion of a more strategic consideration regarding how non-food raw apricots kernels may be sold to consumers.</p> <p>For the reasons outlined above and elsewhere in this Approval Report, FSANZ does not consider labelling as an appropriate option to mitigate acute dietary risks from apricot kernels.</p>

Issue	Raised by	FSANZ response
<p>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 needed amendment, with further clarification as to the basis of the exemptions included to allay any concerns about the safety of exempted products. Noted that the exemption list was not exhaustive, and excluded foods such as apricot jams, persipan or blanched kernels without any apparent reason. However, an exclusion list might cause future problems for enforcement agencies, as new products or existing products that contained raw apricot kernels that were not listed might be potentially in breach of the variation, although they did not present a public health risk. This might hinder industry innovation, discouraging new food product development unless a business was willing to make an application to amend the Code. This could be prohibitively expensive for small to medium size enterprises.</p> <p>The draft variation should be less specific, worded in such a way that raw apricot kernels were only allowed to be added as an ingredient of food if processing would take place to reduce any risk associated with the consumption of the final food. This might include the removal of the cyanogenic glycosides via an appropriate process. Taking this approach, specifying processing of the kernels so they were safe to consume (for example as stone fruit juices or confectionery) 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>FSANZ has amended the drafting to address these issues. See section 2.3.4</p>

Issue	Raised by	FSANZ response
<p>Raised a number of issues in regard to the drafting: What constituted “raw”? It might be that mildly blanched kernels were arguably not raw, but the HCN content might 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>Subclause 3 of the drafting appeared to allow the sale of confectionery in the form of sugar-coated raw apricot kernels, and also allowed any substance derived from raw kernels (including an extract high in HCN) which were contrary to the apparent intent of the variation</p>	<p>Bill Porter</p>	<p>FSANZ has defined raw as the following:</p> <p>The term ‘raw apricot kernel’ refers to the nut-like object found within the shell or stone of <i>Prunus armeniaca</i> either unhulled (with skin) or hulled (without skin).</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 apricot kernels but rather confectionery that used small amounts of apricot kernels as ingredients that are safe for consumption. This exclusion for confectionery is also supported by an ML of 25 mg/kg for confectionery in Standard 1.4.1 (or Schedule 19 of the revised Code).</p> <p>FSANZ has amended the drafting to include a cross reference to Standard 1.4.1 (and Schedule 19 of the revised Code) which lists MLs for HCN in confectionery, stone fruit juices, marzipan and alcoholic beverages. The ML for confectionery addresses the issue of sugar/chocolate coating of apricot kernels</p>
<p>Supported the prohibition on sale of unhulled (skin-on) and hulled (skin-off) apricot kernels. Concerned that the level of variation in HCN in kernels created challenges in developing and administering risk management strategies such as labelling or consumer advice.</p> <p>Concerned that the draft variation might still allow the addition of raw apricot kernels to foods such as cakes, biscuits and confectionery. For example, chocolate-covered apricot kernels (sold as confectionery), or ground up apricot kernels added to a muesli bar (sold as a cake or biscuit). MPI proposed that this might be avoided by an ML in Standard 1.4.1 for cakes, biscuits, oils and confectionery.</p> <p>Medsafe (under the Ministry of Health) had indicated it would not regard apricot kernels as a dietary supplement (given they are presented more like a food)</p>	<p>New Zealand Ministry for Primary Industries (NZMPI)</p>	<p>It was not the intent of subclause 3 to allow the sale of chocolate coated raw apricot kernels but rather confectionery that used small amounts of apricot kernels as ingredients from which the final product was safe for consumption. An example is persipan, a confectionery which is similar to marzipan, but apricot kernels are used instead of almonds</p> <p>http://www.lemke.de/en/produkte/sortiment/persipanmassen.html. The exclusion for confectionery is also supported by an existing ML of 25 mg/kg for confectionery in Standard 1.4.1 (and Schedule 19). Therefore, if a business moved to either sugar or chocolate coat an apricot kernel to avoid the prohibition, the existing ML for confectionery 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>

Issue	Raised by	FSANZ response
<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.</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 was likely to be raw consumption, rather than further processing.</p> <p>MPI had 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>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 USA, 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 confectionery, due to no identified public health and safety concerns, noting that there is an existing ML for confectionery 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>
<p>Raised whether the options had considered the sale of raw apricot kernel skin (as it was high in laetrile), although noted that the draft variation included raw apricot kernels or any substance derived therefrom.</p> <p>The assessment summary and the supporting documents did 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 made them safe to consume. If there was 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>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 proposed in the draft variation 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 2.3.4 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 update the current website advice to refer to the prohibition and that it applies to online as well as retail outlets http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx</p>

Issue	Raised by	FSANZ response
<p>If the recommended regulatory measure was accepted and the sale of raw hulled and unhulled apricot kernels was prohibited (with the exceptions noted in the assessment summary), it would 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>		

2.2 Risk assessment

The full risk assessment was conducted as part of the ISFR Coordinated Food Survey Plan at <http://www.foodstandards.gov.au/science/surveillance/Pages/Combined-survey-and-risk-assessment-for-cyanogenic-glycosides.aspx>.

Public health and safety issues were identified for acute dietary exposure to apricot kernels (see 2.2.1 below). However, there were no public health and safety issues identified in relation to the estimates of chronic dietary exposure to HCN from other plant-based food for the Australian and New Zealand populations, based on the survey data available.

For cassava roots, there was potential for high consumers to exceed the ARfD of 80 µg HCN/kg body weight. However, given the conservative assumptions made in the acute dietary exposure assessment, and the absence of any reports on poisonings in Australia or New Zealand following consumption of properly processed cassava, the estimated potential exposures to HCN was not considered to represent an appreciable health and safety risk.

For bread containing linseed, although the estimated acute dietary exposures resulted in potential exceedances of the ARfD for all population groups assessed, current exposures were not considered to represent a health and safety risk due to the absence of any clinical reports of poisonings or detectable levels of cyanide in the blood of human volunteers following consumption of ground linseed.

FSANZ concluded that there was no appreciable health and safety risk from consumption of these foods for consumers.

2.2.1 Raw apricot kernels

The risk assessment identified that due to high levels of HCN, consumption of raw apricot kernels both unhulled (with skin) and hulled (without skin) poses a public health and safety risk for consumers.

In the ISFR survey, levels of HCN in raw apricot kernels with skin ranged from 1,240-2,820 mg HCN/kg; whereas those without skin ranged from 49 to 440 mg HCN/kg.

An acute dietary exposure assessment was conducted for raw apricot kernels for adults only (see Table 2). As no nutrition survey consumption data were available for this product, the assessment was based on estimated consumption of recommended serve sizes as provided by websites associated with the product (32 kernels/day). The estimated dietary exposure for 32 kernels with skin exceeded the acute health based guidance value (*Acute Reference Dose*, ARfD) by about nine-fold and by around 1.5-fold for kernels without skin. Using the maximum HCN levels in raw apricot kernels found in the ISFR survey (2,820 mg HCN/kg in a blended sample of apricot kernels) and the FSANZ recommended maximum consumption of no more than 4 kernels/day, these kernels with skin would still slightly exceed the ARfD (110-120%) but not for kernels without skin.

Table 2: Estimated acute dietary exposures to total HCN for Australian and New Zealand population groups as a percentage of the acute reference dose (ARfD)

Food	% ARfD*					
	Australia			New Zealand		
	2-6 years	2-16 years	17 years and above	5-6 years	5-14 years	15 years and above
Apricots, canned	30	15	15	3 [#]	15	15
Apricot jam	2	3	2	NC	<1 [#]	<1 [#]
Apricot kernels, with skin (32/d)	NA	NA	910	NA	NA	940
Apricot kernels, with skin (4/d)	NA	NA	110	NA	NA	120
Apricot kernels, without skin (32/d)	NA	NA	140	NA	NA	150
Apricot kernels, without skin (4/d)	NA	NA	20	NA	NA	20
Apricot nectar	35 [#]	7 [#]	20 [#]	3 [#]	35	NC

NC = not consumed.

NA = not applicable. Dietary exposure assessments not conducted for children for this food.

* ARfD = 80 µg HCN/kg bw

[#] P50 Median consumption level used for consumers only, rather than 97.5th percentile (number of respondents <39).

The exceedance of the ARfD by up to nine-fold is of considerable concern for public health and safety because there are multiple published cases of adult and child cyanide poisoning resulting from eating an unspecified number of cooked and/or ground apricot kernels (or pits). These reported cases ranged from clinical signs of mild cyanide poisoning (headache, nausea) right through to severe intoxication resulting in hypotension, coma, convulsions and death (Sayre & Kaymakcalan 1964; Lasch et al 1981; Suchard et al 1998; Akyildiz et al 2010; Cigolini et al 2011; Akil et al 2013). Almost invariably, these published cases only describe presentations at hospitals necessitating clinical intervention.

An estimate of the maximum number of raw apricot kernels that could be consumed before exceeding the ARfD was also undertaken for this product using maximum levels derived from the analytical data from the ISFR survey, for both adults and children. For apricot kernels with skin, it was estimated that adults could consume 3 kernels before the ARfD is exceeded. For children, consuming 1 kernel/day would lead to exceeding the ARfD. For apricot kernels without skin, adults could consume 21 kernels and children could consume 6 kernels/day before the ARfD is exceeded.

It is recognised that this survey analysed a relatively small sample of raw apricot kernels and that the levels of HCN/kg may be more variable. However, it is noted that literature reports suggest the mean range of HCN/kg found in kernels from a variety of different apricot cultivars can be up to 4,090 mg/kg (e.g. Holzbecher et al 1984). A random chance selection of kernels with a higher HCN content would increase the potential health risk.

FSANZ's current recommendation¹⁰ is that children should not consume apricot kernels. If children were to consume these against the recommended advice then, with exceedances occurring at less than 1 unhulled (skin-on) kernel/day, it is very likely that HCN exposure amounts would exceed the health-based guidance value (ARfD).

¹⁰<http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx>

2.2.2 Other apricot kernel containing foods

Various foods containing apricot kernels were analysed for the presence of HCN in the ISFR survey (amaretti biscuits and almond finger biscuits) and in addition, apricot jams and apricot nectar (which may contain trace amounts of HCN via the presence of small amounts of apricot kernels during production) were analysed. These foods were found to not pose a public health and safety risk (Table 2).

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.

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 (USA), the US Food and Drug Administration (FDA) has assigned a GRAS status (Generally Regarded as Safe) to apricot kernel (persic) oil (USFDA).

2.2.3 Levels of HCN in apricot kernels

The following table summarises the currently available data on levels of HCN in apricot kernels:

Table 3: Currently available data on levels of HCN in apricot kernels

Food type	Survey	Number of samples	Total HCN Range mg/kg
Apricot kernels (skin-on)	In 2011 during Queensland poisoning incident	3 blended samples	1,700 to 2,300
Apricot kernels (skin-on)	ISFR survey	18 blended samples ¹¹	1,240 to 2,820
Apricot kernels (skin-off)		10 blended samples	49 to 440
Apricot kernels (skin-on)	In 2014 during WA incident	1 blended sample	>3,000 ¹²
Apricot kernels (skin-on)	Holzbecher et al 1984	Case study from a poisoning incident	4,090

These surveys indicate there is considerable variability in levels of cyanogenic glycoside concentrations in apricot kernels. In addition, the surveys analyse blended samples resulting in an averaging of the HCN concentrations between individual kernels. Individual kernels were not tested. The concentrations in some individual kernels would have been higher than the blended concentrations reported in the survey. The ISFR survey with more samples showed levels higher than reported in the first survey undertaken during the poisoning incident in Queensland. It is unlikely these surveys have identified the true range of cyanogenic glycosides in apricot kernels that are currently available for sale given the restricted number of studies and samples.

¹¹ a 10 g aliquot was taken from the blended sample of about 200-1000 g of apricot kernels for analysis

¹² This is the highest level measured in Australia and New Zealand (although the actual value was not verified).

For example, the maximum mean level of blended samples of kernels will not reflect the absolute maximum level of HCN possible in individual apricot kernels. Support for this arises from the recent poisoning incident in WA and from a case study of poisoning internationally.

2.3 Risk management

Based on survey data in which blended samples of apricot kernels were tested, acute dietary risks (exceedance of the ARfD) have been identified with potentially severe acute potential poisoning associated with the consumption of raw apricot kernels. The concentrations of HCN in individual apricot kernels may be even higher than those reflected in the survey.

HCN is a lethal acute toxin with a steep dose response curve. Doses slightly higher than those producing relatively non-specific symptoms can be fatal. Toxicity across species is similar and animal models have clear relevance to estimation of safe human exposures. Therefore, there is narrowness of the safety margin between the level of HCN in kernels that might be consumed and resulting toxicity. This is reflected in the available human toxicity reports from the poison information centres and the levels of HCN found in overseas reports (up to 4,090 mg/kg) which may be imported into Australia and New Zealand.

During the preparation of the Consultation RIS, FSANZ was notified about a further poisoning incident that occurred in Western Australia in July 2014. The consumer was hospitalised with cyanide poisoning after consuming an unknown number of unhulled raw apricot kernels. The product was recalled from the market due to high HCN levels (i.e. >3000 mg/kg)¹³. The product packaging did contain a warning statement and directions for use with a recommended maximum amount/day of unhulled apricot kernels that could be safely consumed. The website from which the product was purchased (<http://www.oznatureshop.com.au/store/apricot-hemp-seeds/raw-apricot-kernels-per-kilo/c-24/c-84/p-255>) also has a warning statement with a recommended maximum amount/day of unhulled apricot kernels that could be safely consumed¹⁴.

In assessing the Proposal, FSANZ has considered both non-regulatory and regulatory options to appropriately manage the food safety risks posed by raw apricot kernels.

Taking into account the risk assessment conclusions, the focus of FSANZ's risk management measures was on managing the risk from high concentrations of HCN in raw apricot kernels. No further regulatory measures were warranted for the other foods containing cyanogenic glycosides assessed in the ISFR survey.

Risk management measures were needed for raw apricot kernels and for any substance derived from raw apricot kernels which is not further processed to make them safe (i.e. whole raw kernels or kernels that have been ground, milled, cracked or chopped), as kernels in any of these forms are still potentially toxic. As an example, a woman was admitted to North Shore hospital in New Zealand after consuming 60 ground apricot kernels mixed with orange juice (Atkinson, 2006).

The risk assessment on a number of foods derived from apricot kernels which were surveyed indicated there was no potential risk arising from their consumption. The data from the ISFR survey showed that the levels of HCN in apricot kernel-derived foods (amaretti biscuits, almond finger biscuits), apricot jams and apricot nectar did not present public health and safety concerns. Levels of HCN in apricot oil do not pose a risk.

¹³ 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 3000mg/kg could lead to exceedance of the ARfD or poisoning.

¹⁴ The warning statement provided is 'Apricot Kernels contain Hydrocyanic Acid and can be toxic when consuming more than 3 kernels per day.'

There are also other foods derived from apricot kernels (e.g. amaretto liquor)¹⁵ that were not tested in the survey.

Any risk of consumption of processed foods derived from apricot kernels is managed by the processing or cooking of these foods to reduce HCN levels and/or by existing MLs for HCN in the Code¹⁶.

2.3.1 Revisiting the policy on a prohibition versus an ML approach to the regulation of raw apricot kernels derived foods

After the public consultation on the Call for Submissions report and in further discussions with enforcement agencies, FSANZ revisited the following questions:

- (a) Would an ML approach be more appropriate or not; and
- (b) if not, would the current non-ML approach (prohibition) really improve on the current situation? That is, was FSANZ merely replicating the existing Food Acts' 'unsafe' offences?

There has been no change to the approach FSANZ has adopted throughout the assessment of this Proposal in relation to the inappropriateness of setting an ML for whole apricot kernels. Further details on this can be found in the Regulation Impact Assessment at Attachment D.

In regard to the policy of an ML approach for apricot kernel derived foods, FSANZ's policy decision is to permit the non-retail sale of apricot kernels to enable the sale of safe foods derived from them. However, during public consultation, an issue was raised in regard to whether the sale of apricot kernel derived foods should be based on a general provision of safety or by setting an ML. FSANZ considers addressing this issue by a provision in the Code is necessary because relying on a general provision of safety under the Food Acts may result in suppliers of apricot kernels marketing a potentially unsafe product i.e. containing cyanogenic glycosides at an unsafe level. FSANZ does not have concerns with current apricot kernel containing products. FSANZ also wishes to permit innovation of safe products as suggested in the submission from the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources (the Departments).

The analysis of these options is outlined below, but it is important to note that FSANZ has not changed its policy options since the Call for Submissions.

Option 1 Provisions as drafted for the Call for Submissions (Attachment C)

The original drafting prohibited the sale of raw apricot kernels, both unhulled (with skin) and hulled (without skin), under Standard 1.4.4 – Prohibited and Restricted Plants and Fungi. This prohibition applied to any substance derived from raw apricot kernels, with some exceptions from the prohibition for alcoholic beverages, oil, flavourings, stone fruit juices, marzipan, cakes, biscuits and confectionery derived from apricot kernels.

¹⁵ Amaretto is a sweet, almond-flavoured, Italian liqueur. It is made from a base of apricot kernels or almonds, sometimes both

¹⁶ Confectionery, stone fruit juices, marzipan and alcoholic beverages

Pros	Cons
Exempted foods that FSANZ had identified as having no public health and safety concerns	The exemption list was not exhaustive, and excluded foods such as apricot jams, persipan or blanched kernels
	It was identified that the exemption list may cause problems for enforcement agencies in the future, as new products or existing products that contain raw apricot kernels that are not on the exemption list may be 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.

Option 2 (for apricot kernel derived products only) Provisions as amended following public consultation specifying that a processing step is needed for use as an ingredient to ensure safe levels (Attachments A and B)

Pros	Cons
With proper treatment or processing, raw apricot kernel derived foods are safe for human consumption, even though whole, unprocessed raw apricot kernels pose an acute dietary risk; particularly for children.	Lacks prescriptions and relies on interpretation from jurisdictions on what is an unsafe food ¹⁷ .
Clarifies that apricot kernels can still be used as an ingredient provided they are adequately prepared for safe consumption. This is broadly consistent with the requirements for sweet cassava and bamboo shoots that exist in the Code under Standard 1.2.6 Direction for Use and Storage.	
Facilitates development of new safe apricot kernel derived foods.	

Option 3 Generic ML for apricot kernel derived foods

A safe generic health-based ML for all apricot-kernel derived foods could be considered. Note that the data are too limited to set an ML on an achievability basis which is the normal approach in setting an ML for a contaminant.

Pros	Cons
Prescription and certainty for enforceability and would provide a specific level to which all apricot kernel containing foods should adhere to.	Not consistent with minimal effective regulation
No impediment to developing new safe apricot kernel derived foods.	There are no public health and safety issues we can attribute to the sale of apricot kernel derived foods that are currently on the market from our recent surveys.
	Contributes to unnecessary costs for both jurisdictions and businesses if there are no apparent public health and safety issues. For government enforcement agencies, they would need to develop strategies for ensuring that businesses comply with the maximum level. This would have a cost.

¹⁷ Note that FSANZ is preparing future guidance material on the safety of apricot-kernel derived foods for use by jurisdictions if the amendments to the Code are eventually gazetted

Option 4 No provision for a treatment or processing step and rely only on food acts provisions prohibiting sale of unsafe food

Pros	Cons
Maximum flexibility for industry to determine whether a food is safe and for jurisdictions to interpret the safe food acts	Inadequate certainty for enforcement purposes.
	Costs associated with managing unnecessary responses to the detection of hydrocyanic acid in new apricot kernels derived foods.
	Possibly encourage more gaming by businesses trying to avoid the overall prohibition on raw apricot kernels under standard 1.4.4 if there was no reference to a treatment or processing step being prescribed in the Code to make the food safe for consumption.

FSANZ has concluded that option 2 above and the reference to safe processing or treatment (see section 2.3.2 below) offers the best net benefit and does not impose an unnecessarily prescriptive requirement in the Code where the evidence base does not support such a measure.

2.3.2 Proposed risk management options

Before public consultation, FSANZ considered that the 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) was likely to have the greatest net benefit and was the preferred option. The determination that this option was likely to have the greatest net benefit was based on qualitative analysis due to difficulty obtaining quantitative information from industry.

Subject to full consideration of the submissions received on the Call for Submissions, the OBPR and the WTO notification, the following options were again considered to manage the risk of consumption of apricot kernels at Approval:

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 risk assessment indicates there is a significant risk arising from the consumption of apricot kernels.

Maintaining the status quo is considered to be an inappropriate risk management measure because:

- The consumption of raw apricot kernels would continue, including health risk to consumers, particularly children, due to high levels of HCN.
- There is a lack of scientific evidence for the use of raw apricot kernels for cancer treatment as well as the risk to public health and therefore consumers would continue to be misled.
- The effectiveness of website advice may be limited, as it is dependent on consumers seeking and being aware of this information.

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 then acting 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.
- 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 it is impossible to predict a safe number of kernels that could be consumed per day (refer to DRIS for more information). 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 occur¹⁸.
- 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.

Option 3 – Set a maximum level of HCN

This regulatory option involves setting a maximum level (ML) in Standard 1.4.1 of the current Code (and Standards 1.1.1, 1.2.1 and 1.4.4 of the revised Code) for unhulled (skin-on) and hulled (skin-off) raw apricot kernels. 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.

FSANZ considers that it is inappropriate to set an ML given the available evidence. An ML would not be an effective mitigation measure for HCN in raw apricot kernels for the following reasons:

- The ML set by FSANZ would have to be set so low that very few apricot kernels would be compliant and it would have the same practical effect as prohibition.
- The risk may be underestimated based on current information. 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. Higher values have also been reported in the literature.

¹⁸ 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.

Overall, the amount of information available on the highest levels of HCN which may be found in apricot kernels will be an underestimate of the total apricot kernel supply. An ML would need to be set at a very low level in order to be protective of health, taking into account the possible variability within a product batch.

The setting of an ML would require the development of a sampling plan. It would be impractical to test individual kernels. Therefore, an ML based on testing a homogeneous mix would have to take account of the variability in order to be protective against the presence of individual kernels which contain sufficiently high levels of HCN to place an individual at risk. 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.

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. 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.

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, this option would lead to a reduction in the risk of future poisoning. 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). 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 safeguard consumers.

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 (and Standards 1.1.1, 1.2.1 and 1.4.4 of the revised Code), with additional requirements that raw apricot kernels must not be used as an ingredient in food unless subject to processing or treatment to render them safe for consumption (as amended following consultation). The intent of Option 5 is not to prohibit the safe use of raw apricot kernels as an ingredient in other foods (such as confectionery). Nor does it prohibit the sale of whole apricots containing raw apricot kernels. Businesses can still sell raw apricot kernels to other businesses for further processing.

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.

This risk management measure reduces significantly the risk of harm arising from the consumption of raw apricot kernels that the risk assessment has identified. This measure also reduces the potential for consumers to be misled by claims that kernels are beneficial in treatment of cancer. As can be seen 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.

The following table presents a comparison of the various options and their implications for permissions. Only Option 5 prohibits the direct retail sale to consumers of raw (unhulled and hulled) apricot kernels). The intent is to capture all types of direct retail sale to consumers, including a sale in conjunction with other services (such as sale to a consumer by a naturopath).

	Option 1 ¹⁹	Option 2 ²⁰	Option 3 ²¹	Option 4 ²²	Option 5 ²³
Direct retail sale of raw skin-on apricot kernels	Permitted	Permitted	Permitted	Prohibited	Prohibited
Direct retail sale of raw skin-off apricot kernels	Permitted	Permitted	Permitted	Permitted	Prohibited
Wholesale of raw skin-on apricot kernels	Permitted	Permitted	Permitted	Permitted	Permitted
Wholesale of raw skin-off apricot kernels	Permitted	Permitted	Permitted	Permitted	Permitted
Processed foods derived from apricot kernels (provided processing or treatment step is undertaken to render the food safe for human consumption)	Permitted	Permitted	Permitted	Permitted	Permitted
Whole apricots which contain raw apricot kernels	Permitted	Permitted	Permitted	Permitted	Permitted

2.3.3 Final risk management option at Approval

The determination of which option is likely to have the greatest net benefit was based on qualitative analysis. None of the proposed options would reduce risk to zero and it is acknowledged that most will impose additional costs.

The preferred option (Option 5) is prohibition from sale of raw apricot kernels for the following reasons:

- A significant potential harm exists from high dietary levels of HCN particularly for children and this is reflected in the data from poisoning information centres in Australia and New Zealand (refer to Tables 4 to 8 in the DRIS) and from overseas reports.

¹⁹ Option 1: Maintain the status quo

²⁰ Option 2: Mandatory labelling of all raw apricot kernels

²¹ Option 3: Set a maximum level of HCN all raw apricot kernels

²² Option 4: Prohibition on the sale of raw skin on apricot kernels

²³ Option 5: Prohibition on the sale of all raw apricot kernels

- The *status quo* option in parallel with FSANZ's current website advice is not likely to be an effective measure as it depends on consumers seeking and noticing and taking account of this information.
- There is uncertainty surrounding the absolute maximum levels of HCN that could potentially be present in raw apricot kernels which makes it extremely difficult to set an ML or consider advice to consumers via labelling. This poses an additional risk in that FSANZ's advice would need to be continually updated if higher levels were found in apricot kernels on the market²⁴.
- 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.
- Even if an ML was set, it would be at such a low level that, in effect, it would lead to a similar outcome as the proposed prohibition.
- Prohibition 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
- Prohibition protects new consumers unaware of the risks of consuming raw apricot kernels and from the unproven health claims associated with the sale of some apricot kernels, supporting the objective of prevention of misleading or deceptive conduct.

This prohibition relates only to food use of apricot kernels. Nor does it prohibit the sale or use of foods derived from apricot kernels which do not pose health risks (e.g. kernels as an ingredient in other foods).

FSANZ has had regard to and taken into account the Decision Regulation Impact Statement (DRIS) prepared for this proposal. The DRIS reflects the requirements of the decision-making framework set out in the Council of Australian Governments Best Practice Regulation Guide. The DRIS considers that there may be insufficient evidence to demonstrate that an intervention will result in a sufficiently large reduction of the presently unclear level of harm to result in a net benefit to the community as a whole. On this basis, the DRIS recommends that the status quo be maintained.

However, FSANZ has decided on a regulatory option despite the conclusion of the DRIS. This decision is based on the evidence provided in the risk assessment and after careful consideration of the efficacy of various risk management options in managing the identified risks and protecting public health and safety. FSANZ is satisfied that the potential costs of the proposed measure will not exceed the value of the anticipated direct and indirect benefits to the public.

2.3.4 Amendments to the drafting since the Call for Submissions

In order to address several issues raised in submissions, FSANZ has revised the drafting. The revised draft variations are at Attachment A and B.

FSANZ has amended the original drafting proposed at the Call for Submissions to provide the following:

²⁴ The current advice is based on a maximum limit of 2,820 mg/kg; however, overseas levels of up to 4,010 mg/kg have been reported.

- A provision that prohibits the direct sale of raw apricot kernels to the public at retail sale (catering would be covered under this retail sale clause)
- A provision that expressly permits the use of raw apricot kernels as an ingredient in food provided that processing or treatment step is undertaken to render the food safe for human consumption. This avoids the difficulty of imposing on those who sell ingredients (apricot kernels) a requirement that relates to the final food produced by others (e.g. a requirement for a process or treatment that renders the final food safe).

This revised drafting allows the supply of raw apricot kernels to other manufacturers (e.g. from a wholesaler to a food manufacturer) provided that a processing or treatment step is undertaken to render the food safe for human consumption. FSANZ will assist jurisdictions in deciding on the safety of apricot-kernel derived foods by provision of future guidance material/information before gazettal of the standard.

- The removal of the exemption list which previously listed the following foods: alcoholic beverages, oil, flavourings, stone fruit juices, marzipan, cakes, biscuits and confectionery derived from apricot kernels.

This avoids future enforcement issues that may arise for new products not previously included in the exemptions list. These foods will now be captured by the new general clause referring to a treatment or processing step being required to render the food safe for human consumption.

- A provision that preserves the application of MLs set by Standard 1.4.1 (or Schedule 19 of the revised Code) for the four foods²⁵ (only) in the Table to clause 4.

The existing ML for confectionery addresses the issue of sugar/chocolate coating of apricot kernels.

- Inclusion of the term 'blanched' in the definition of 'raw apricot kernels' in order to recognise that removal of the skin via blanching²⁶ does not mean that raw apricot kernels are then in a cooked state.

2.3.5 Additional risk management measures

FSANZ is preparing guidance material on the safety of apricot-kernel derived foods for use by jurisdictions upon gazettal. FSANZ proposes that post-market surveillance is undertaken in two years' time to assess the availability of apricot kernel foods on the market following the prohibition.

FSANZ has also raised the issue of non-food uses of apricot kernels with state, territory and New Zealand jurisdictions and implementation of a prohibition on apricot kernels with the ISFR Secretariat.

2.3.6 Internet sales of apricot kernels

During targeted consultation, concerns were raised that the prohibition of apricot kernels sold over the internet would be difficult to enforce and may result in a continuing market for apricot kernels.

²⁵ Alcoholic beverages, stone fruit juices, marzipan and confectionery.

²⁶ 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.

FSANZ approached both the New Zealand Commerce Commission (NZCC) and the Australian Competition and Consumer Commission (ACCC) about their views regarding actions they might take against the internet sale of apricot kernels; specifically, sales via the internet with associated misleading and unsubstantiated claims even if a prohibition was in place under the prohibited botanicals standard.

The NZCC indicated that it would have jurisdiction over overseas sites advertising goods such as apricot kernels, where they are shipped to New Zealand, but it was 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 was 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 Policy²⁷ and on a case-by-case basis.

The Compliance and Enforcement Policy includes a number of factors to determine enforcement priority; demonstrating substantial consumer detriment is one of the factors considered. Another factor is whether the relevant specialist 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 has indicated it would certainly consider whether the *Competition and Consumer Act 2010* could be used to protect consumers.

2.4 Decision

At Approval, the options available to the FSANZ Board were as follows:

- approve the draft variation to Standard 1.4.4 of the current Code that was proposed in the call for submissions.
- approve that draft variation subject to such amendments as considered necessary, including providing draft variations to the revised Code.
- reject the draft variation.

After careful consideration of the available evidence and the requirements of the FSANZ Act, FSANZ concluded that a regulatory approach (partial prohibition) was warranted. The draft variation as proposed following assessment was therefore approved with amendments.

²⁷ <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy>

The approved draft variation, as varied after consideration of submissions, and related explanatory statements are at Attachment A and B respectively. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

The approved draft variation to Standard 1.4.4 of the current Code takes effect on gazettal.

The approved draft variation to Standards 1.1.1, 1.2.1 and 1.4.4 of the revised Code takes effect on 1 March 2016, which is the date on which the revised Code comes into effect.

The draft variation on which submissions were sought is at Attachment C.

2.5 Risk communication

2.5.1 Consultation

In April 2012 and November 2013, targeted consultations were undertaken seeking data and/or information on the nature, size and costs of production of apricot kernels for either the domestic and/or import industry. FSANZ identified 46 businesses (importers, producers and retailers) in Australia and New Zealand, and they were approached via email or letter for this information.

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 Proposal. Every submission was considered and reviewed by FSANZ staff, who examined the issues identified and prepared a response (see Table 1). All comments are valued and contribute to the rigour of our assessment.

FSANZ called for public comment from 16 December 2014 to 10 February 2015 after assessing the Proposal and preparing a draft variation. The above businesses and other key stakeholders (e.g. stone fruit manufacturers, Horticulture Australia and New Zealand, canning and dried fruit manufacturers) were also notified of the Call for Submissions.

FSANZ also undertook further targeted consultation with jurisdictions in March 2015 to address issues raised in public submissions. This included the revised drafting detailed in section 2.3.2.

The Call for Submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Every submission was considered by the FSANZ Board.

The FSANZ Board's decision has been notified to the Forum. If the decision is not subject to a request for a review, the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.5.2 World Trade Organization (WTO)

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. Amending the Code to prohibit the sale of raw apricot kernels, both unhulled (with skin) and hulled (without skin) and any substance derived from raw apricot kernels which is not processed further may have an effect on international trade. Most apricot kernels used in Australia (approximately 20,000 kg per annum worth approximately \$600,000 to the apricot kernel industry) are 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, most kernels used there are imported. Advice from the New Zealand authorities is that an average of 264 kg per annum was imported into New Zealand between 2011 and 2013, with 1280 kg being imported in 2014 (which included a single shipment of 1000 kg). 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.

The Chinese Government made a submission which raised the following issues:

- 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 was a qualitative evaluation, FSANZ should, as a transitional measure, undertake a quantitative approach and set MLs.
- FSANZ should strengthen the enforcement of misleading claims associated with apricot kernels.
- Because apricot kernels consisted of both sweet and bitter varieties, FSANZ should undertake a classification and risk assessment of both varieties and then on this classification basis set MLs for HCN.

2.5.2.1 FSANZ Evaluation of WTO response

FSANZ has identified a significant acute public health and safety dietary risk from exposure to HCN from consumption of raw apricot kernels and remains concerned that poisoning incidents are still occurring despite voluntary warning statements on some products. FSANZ has acted to partially prohibit the sale of apricot kernels to address the identified public health and safety risk.

FSANZ acknowledged in the Consultation Regulation Impact Statement (CRIS) that the prohibition is based on qualitative analysis due to difficulty obtaining quantitative information from industry.

The prohibition relates only to the direct retail sale of apricot kernels. It does not extend to a prohibition on the use of foods derived from apricot kernels which do not pose health risks (e.g. when kernels are used as an ingredient in other foods provided a treatment or processing step is undertaken to render the final food safe for consumption).

FSANZ does not consider the option of setting an ML is open for the reasons identified in this Approval Report.

FSANZ has no powers under the FSANZ Act to regulate therapeutic products (this is a matter for the TGA in Australia and Medsafe in New Zealand), although therapeutic claims are prohibited under Standard 1.2.7.

Sweet versus bitter varieties of apricot kernels

FSANZ investigated the possibility of classifying sweet and bitter varieties of kernels, and then on this classification basis, setting maximum limits (MLs) for HCN. Previous research has analysed raw apricot kernels after removal of the skin (with the exception of the Haque and Bradbury (2002)²⁸ and Yildirim and Askin (2010)²⁹ studies) and classified them according to sweet or bitter by the HCN levels. A summary is presented in the table below. Note that to provide a better comparison, units were standardised to grams/100 g of seeds and values corresponding to HCN or amygdalin from the studies were listed.

Kernels	Cyanide (HCN) mg/100 g seeds	Amygdalin g/100 g seeds	Reference
Not classified as bitter or sweet	81	1.3	Haque and Bradbury (2002)
Bitter	300-480	5-8	Gomez et al (1998)
Bitter	270 to 390	4.5 to 6.5	Femenia et al (1995)
Bitter	264 to 336	4.4 to 5.6	Yildirim et al (2010)
Sweet	trace	Trace	Gomez et al (1998)
Sweet	0	0	Femenia et al (1995)
Sweet	52 (36 to 96)	0.86 (0.6 to 1.6)	Yildirim and Askin (2010)
Apricot kernels (skin-on): not classified as bitter or sweet	1,240 to 2,820 (124 to 280 mg/100 g)		FSANZ (2014)
Apricot kernels (skin-off): not classified as bitter or sweet	49 to 440 (4.9 to 44 mg/100 g)		
Skin-off Kernels labelled North (bitter) ³⁰	440 mg/kg (44 mg/100 g)		FSANZ (2014)
Skin-off Kernels labelled South (sweet)	220 mg/kg (22 mg/100 g)		FSANZ (2014)

FSANZ has decided that the prohibition on retail sale should apply to both skin-on and skin-off varieties and that there should be no differentiation between sweet or bitter varieties because:

- of the variability in levels and distribution of HCN within seed varieties which can vary from year to year (Krafft et al 2012) similar to almonds (Yildirim et al 2014)
- bitter and sweet kernels (with skin-on) are similar in appearance, which makes them difficult for consumers to differentiate between the two types
- there is overlap between levels of HCN in kernels classified as sweet or bitter
- at the higher levels (e.g. 440 mg/kg from the FSANZ survey) there is still a risk to public health and safety³¹
- bitter and sweet kernels cannot be distinguished apart from analysing for HCN levels; however, this would pose enforcement difficulties, particularly if products were not labelled as sweet varieties, and lead to similar costs for industry to meet a safe maximum level of HCN
- FSANZ does not currently have evidence that sweet kernels are on sale in Australia or New Zealand.

The Chinese Government also requested that FSANZ clarify:

²⁸ Apricot stones were cracked open and kernels ground in a pestle and mortar

²⁹ Extracted seeds were ground by a blender

³⁰ FSANZ understands that 'north' means bitter and south means (sweet) as suggested by the Health Canada (2009) website information <http://www.hc-sc.gc.ca/fn-an/pubs/secureit/2009-apricots-abricots/index-eng.php>.

³¹ Our calculations show that at this level children could only consume a maximum of 6 kernels/day

- whether cooked apricot kernels (which have been treated by heating, baking etc) with reduced levels of HCN, should also be included in the current exemption list
- if apricot kernel-containing products other than the currently exempted foods will be exempt (suggested that Australia exempt all products excluding raw apricot kernels so as not to cause unnecessary obstacles to international trade)
- how Australia will manage the prohibition of raw apricot kernels as foods.

In regard to the first dot point, the approved draft variations permit the use of kernels as an ingredient in food if treatment or processing step renders the food safe.

In terms of management, the partial prohibition on the sale of raw apricot kernels will be a matter for enforcement agencies in Australia and New Zealand.

2.6 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.6.1 Section 59

2.6.1.1 Cost benefit analysis

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs arising from a food regulatory measure developed for this Proposal would outweigh the direct and indirect benefits to the community, Government and industry that arise from the measure.

FSANZ prepared a CRIS (ID No. 16574) for the Call for Submissions to assist in the development of a Decision Regulation Impact Statement (DRIS) (ID No. 14920) and further consideration by FSANZ.

The CRIS and its cost benefit analysis recommended prohibition as the appropriate regulatory measure.

In contrast, the DRIS recommended the Status Quo as its preferred option. The DRIS did so as it considered that there was insufficient information available to demonstrate that an intervention will result in a sufficiently large reduction of the presently unclear level of harm to offset costs to industry to demonstrate a net benefit to the community as a whole. The DRIS also reflects the decision-making framework prescribed in Council of Australian Governments Best Practice Regulation Guide, which is a policy document.

FSANZ took account of the CRIS and to the DRIS and had careful regard to each.

FSANZ decided to adopt a regulatory approach (partial prohibition) on the basis that it was satisfied that there was an identified risk to public health and safety and that this regulatory response was the most effective available to address that risk. In making that decision, FSANZ accepted that there may be insufficient information available to inform fully an economic cost benefit analysis. However, it was satisfied that a regulatory response was required and warranted, having regard to the evidence and to the requirements of the FSANZ Act, which provide that the protection of public health and safety is the primary objective in standards development.

2.6.1.2 Other measures

During the public consultation period, some submitters claimed that raw apricot kernels have therapeutic value and that they should not therefore be prohibited. Submitters suggested that other risk management options may be more appropriate: such as labelling; setting an ML; and/or specifying processing requirements.

For the reasons listed elsewhere in this Approval Report and in the DRIS, FSANZ is satisfied that a partial prohibition, as set out in the approved draft variations, is the most cost-effective food regulatory measure available to address the identified risk.

2.6.1.3 Any relevant New Zealand standards

The proposed draft variations will apply in both Australia and New Zealand.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

FSANZ considered the three objectives in subsection 18(1) of the FSANZ Act before making its decision.

2.6.2.1 Protection of public health and safety

The FSANZ Act requires FSANZ to have regard to the fact that the primary objective in standards development is the protection of public health and safety. FSANZ concluded that a partial prohibition as provided by the approved draft variations would best meet this statutory objective.

2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The issue of labelling raw apricot kernels to enable consumers to make informed decisions was considered in the CRIS and DRIS. For the reasons outlined above, FSANZ was not satisfied that labelling of apricot kernels to be an appropriate risk management measure.

2.6.2.3 The prevention of misleading or deceptive conduct

FSANZ notes the submission from the Cancer Council of Australia that the available scientific evidence does not support consumption of apricot kernels as a cancer treatment and 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 <http://iheard.com.au/question/eating-apricot-kernels-cure/>.

The partial prohibition on the sale of raw apricot kernels protects consumers unaware of risks of consumption of raw apricot kernels and from unproven associated health claims, thereby supporting the objective of prevention of misleading or deceptive conduct.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has assessed and characterised the risk from consuming HCN in raw apricot kernels. This risk assessment (SD1) has considered the best available information (national and international), including animal and human toxicity, relevant to the safety of raw apricot kernels.

- **the promotion of consistency between domestic and international food standards**

There are no international standards for raw apricot kernels although some other countries regulate other foods containing cyanogenic glycosides. However, there is no consistent international regulatory approach (see SD1).

FSANZ notes that the European Food Safety Authority (EFSA) has now been formally asked by the European Commission to provide a scientific opinion on the acute health risks related to the presence of hydrocyanic acid in apricot kernels and products derived from apricot kernels. The official completion date is the end of October 2015³².

- **the desirability of an efficient and internationally competitive food industry**

The approved draft variations impose only a partial prohibition. That is, on direct retail sale of raw apricot kernels. Kernels can still be imported into, sold and used in both Australia and New Zealand as an ingredient in food provided processing and treatment ensures safety.

The DRIS details the considerable effort undertaken by FSANZ to notify and engage industry and to understand and assess the potential impacts on industry. Industry engagement remained limited. After the Call for Submissions and WTO notification, FSANZ received no submissions from industry. One WTO Member country considered that the prohibition may impact on international trade. The issues raised have been addressed in section 2.5.2

Previously, FSANZ had managed to identify only one business that imports/produces greater than 500 kg of apricot kernels per year. Based on the information collected in 2013 (from three respondents) approximately 20,000 kg of apricot kernels for human consumption are imported into / produced in Australia every year. The selling (retail) price is around \$30 per kilogram.

Therefore, the current data suggests that the total value of the apricot kernel industry in Australia is approximately \$600,000. FSANZ approached 46 businesses in both Australia and New Zealand to obtain this information.

A submission from the New Zealand Ministry for Primary Industries indicated that between 2011 and 2013, there was an average of 264 kg imported into New Zealand. In 2014, approximately 1280 kg were imported; the increase due to a single shipment from Turkey.

Therefore, taking these considerations into account, in particular the small size of the market in Australia and New Zealand, there would appear to be minimal impacts on trade.

- **the promotion of fair trading in food**

No fair trading issues have been identified for the purposes of this Proposal.

³² <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL>

- any written policy guidelines formulated by the Ministerial Council³³

No Policy Guideline is applicable.

3 Transitional arrangements

3.1 Transitional arrangements for Code revision

FSANZ has completed a review of the Code undertaken under Proposal P1025 in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the revised Code will commence on 1 March 2016 (following gazettal on 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. The approved variation at Attachment B varies the revised Code on 1 March 2016 to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A which commences on gazettal.

4 Implementation and review

State and territory regulatory agencies (Australia) and the New Zealand Ministry for Primary Industries are responsible for managing the prohibition of raw apricot kernels as foods. The Australian Department of Agriculture and the New Zealand Ministry for Primary Industries are responsible for imported foods in their respective countries.

FSANZ will prepare guidance material for regulatory agencies to assist in future enforcement activities. This could include guidance on either the types of processing that are likely to render foods containing raw apricot kernels as an ingredient safe for consumption and/or guidance on the types of products containing raw apricot kernels as an ingredient that are likely to be safe for consumption.

In response to concerns from state and territory regulatory agencies, FSANZ will conduct post-market monitoring two years after implementation of the prohibition. This will examine whether foods are being sold to consumers which contain apricot kernels as an ingredient, but which have not undergone processing or treatment to render them safe for human consumption and, if concerns arise, an evaluation of HCN levels in apricot-kernel containing foods on the market.

Consumers will still be able to obtain raw apricot kernels from fresh whole apricots. Because of this, FSANZ will maintain the current website advice at <http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx>.

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³³ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

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Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code* and related Explanatory Statement
- B. Approved draft variation to the revised *Australia New Zealand Food Standards Code* and related Explanatory Statement (commencing 1 March 2016)
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)
- D. COAG Decision Regulation Impact Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1016– Hydrocyanic Acid in Apricot Kernels & other Foods) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1016 – Hydrocyanic Acid in Apricot Kernels & other Foods) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] Standard 1.4.4 is varied by –

[1.1] inserting after clause 2 –

“3 Raw apricot kernels

(1) Raw apricot kernels must not be sold in a retail sale.

(2) Raw apricot kernels must not be used as an ingredient in a food unless the kernels have been or will be subject to processing or a treatment that renders them safe for human consumption.

(3) To avoid doubt, nothing in this clause prevents the sale of apricots containing their raw apricot kernels or the use of such apricots as an ingredient in a food.

(4) Nothing in this clause affects the operation of clause 4 of Standard 1.4.1.

(5) For the purposes of this clause –

raw apricot kernels means the nut found within the hard shell or stone of *Prunus armeniaca* and includes hulled, dehulled, blanched, ground, milled, cracked, chopped or whole kernels.

(6) Subclause 1(2) of Standard 1.1.1 does not apply in relation to any variation made by Food Standards (Proposal P1016 – Hydrocyanic Acid in Apricot Kernels & other Foods) Variation.”

[1.2] updating the Table of Provisions to reflect these variations.

Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1016 to consider the risks posed by cyanogenic glycosides in plant-based foods. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation to Standard 1.4.4.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation³⁴, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved draft variations to Standard 1.4.4 to impose a prohibition on the retail sale of raw apricot kernels and to restrict the use of raw apricot kernels as an ingredient. This is due to the identified risk to public health and safety of raw apricot kernels as a food for sale.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1016 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 December 2014 for an eight-week consultation period.

A Regulation Impact Statement was required because the proposed variations to Standard 1.4.4 were likely to have an impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

³⁴ convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1.1] inserts new clause 3 into Standard 1.4.4 – Prohibited And Restricted Plants And Fungi.

Subclause 3(1) prohibits the retail sale of raw apricots kernels.

Subclause 3(2) prohibits raw apricot kernels being used as an ingredient in food unless the kernels have been or will be subject to processing or treatment that renders them safe for human consumption. The exemption applies in relation to kernels that processing or treatment renders safe before or after the kernels' use or addition to a food as an ingredient.

Subclause 3(3) states that nothing in clause 3 prevents apricots containing raw apricot kernels from being added to food or offered for sale as a food.

Subclause 3(4) states that clause 3 does not affect the operation of Standard 1.4.1.

Subclause 3(5) provides a definition of the term 'raw apricot kernels' for the purposes of clause 3.

Subclause 3(6) states that the stock-in-trade exemption provided by subclause 1(2) of Standard 1.1.1 will not apply in relation to the amendments.

Item [1.2] updates the Table of Provisions to reflect the insertion of the new clause.

Attachment B – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



***Australia New Zealand Food Standards Code* – Revocation and Transitional Variation 2015 (Proposal P1016 – Hydrocyanic Acid in Apricot Kernels & other Foods)**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 2 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX.

1 Name of instrument

This instrument is the *Australia New Zealand Food Standards Code — Revocation and Transitional Variation 2015 (Proposal P1016– Hydrocyanic Acid in Apricot Kernels & Other Foods)*.

2 Commencement

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions —2014 Revision.

3 Variation of Standard 1.1.1

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

SCHEDULE

[1] **Standard 1.1.1** is varied by

[1.1] omitting paragraph 1.1.1—10(5)(e), and substituting

- “(e) kava or any substance derived from kava;
- (f) if the food is for retail sale – raw apricot kernels.”

[1.2] omitting paragraph 1.1.1—10(6)(i), and substituting

- “(i) kava or any substance derived from kava;
- (j) raw apricot kernels.”

[1.3] inserting after Note 3 following subsection 1.1.1—10(6)

“ **Note 4** Relevant permissions for raw apricot kernels are contained in Standard 1.4.4.”

[2] **Standard 1.1.2** is varied by inserting in subsection 1.1.2—3(2) in appropriate alphabetical position

“**raw apricot kernels** means the nut found within the hard shell or stone of *Prunus armeniaca* and includes hulled, dehulled, blanched, ground, milled, cracked, chopped or whole kernels.”

[3] **Standard 1.4.4** is varied by inserting after section 1.4.4—4

“**1.4.4—5 Exception relating to raw apricot kernels**

Raw apricot kernels may be used as an ingredient in a food for sale if the kernels have been or will be subject to processing or a treatment that renders them safe for human consumption.”

Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1016 to consider the risks posed by cyanogenic glycosides in plant-based foods. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved draft variations to Standards 1.1.1, 1.1.2 and 1.4.4.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation³⁵, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved draft variations to Standard 1.1.1, 1.1.2 and 1.4.4 to impose a prohibition on the retail sale of raw apricot kernels and to restrict the use of raw apricot kernels as an ingredient. This is due to the risk to public health and safety of raw apricot kernels as a food for sale.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1016 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 16 December 2014 for an eight-week consultation period.

A Regulation Impact Statement was required because the proposed variations to Standard 1.4.4 were likely to have an impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

³⁵ convening as the Australia and New Zealand Food Regulation Ministerial Council

6. Variation

Item [1] of the Schedule to the Variation amends Standard 1.1.1

Item [1.1] varies subsection 1.1.1—10(5) by inserting paragraph (f) into that subsection. The effect of paragraph 1.1.1—10(5)(f) is to prohibit the retail sale of raw apricots kernels.

Item [1.2] of the Schedule varies subsection 1.1.1—10(6) by inserting paragraph (j) into that subsection. The effect of paragraph 1.1.1—10(5)(j) is to prohibit raw apricots kernels from being an ingredient in or component of a food for sale unless expressly permitted by the Code. Subsection 1.1.1—10(6) provides that this prohibition does not extend to raw apricot kernels that are in a food for sale by natural occurrence, such as apricots containing their kernels.

Item [2] of the Schedule amends Standard 1.1.2. It varies subsection 1.1.2—3(2) by inserting into that subsection a definition of a raw apricot kernel. A raw apricot kernel is defined to mean the nut found within the hard shell or stone of *Prunus armeniaca*. The term is defined to include hulled, dehulled, blanched, ground, milled, cracked, chopped or whole kernel or kernels.

Item [3] of the Schedule amends Standard 1.4.4 by inserting section 1.4.4—5. The new section permits raw apricot kernels to be used as an ingredient in a food for sale if the kernels have been or will be subject to processing or a treatment that renders them safe for human consumption. The exemption applies in relation to kernels that processing or treatment renders safe before or after the kernels use or addition to a food as an ingredient.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (Proposal P1016 – Hydrocyanic Acid in Apricot Kernels & Other Foods) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1016 – Hydrocyanic Acid in Apricot Kernels & Other Foods) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

SCHEDULE

[1] **Standard 1.4.4** is varied by

[1.1] inserting after clause 2

“3 Raw apricot kernels prohibited

(1) For the purposes of this clause –

raw apricot kernels means the edible nut found within the hard shell or stone of *Prunus armeniaca* and includes dehulled, ground, milled, cracked, chopped or whole kernels.

(2) Raw apricot kernels or any substance derived therefrom must not be intentionally added to food or offered for sale as a food.

(3) Subclause 2 does not apply to –

- (a) alcoholic beverages;
- (b) oil;
- (c) flavourings;
- (d) stone fruit juices;
- (e) marzipan;
- (f) cakes;
- (g) biscuits; and
- (h) confectionery.

(4) To avoid doubt, subclause 2 does not prevent apricots containing raw apricot kernels from being added to food or offered for sale as a food.

(5) Subclause 1(2) of Standard 1.1.1 does not apply in relation to any variation made by *Food Standards (Proposal P1016 – Hydrocyanic Acid in Apricot Kernels & Other Foods) Variation*.”

[1.2] updating the Table of Provisions to reflect this variation.

**Attachment D – COAG Decision Regulation Impact Statement
(OBPR ID: 14920)**



Hydrocyanic Acid in Apricot Kernels & Other Foods



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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)³⁶.

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, 2008³⁷). 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.³⁸

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 foods³⁹, Food Standards Australia New Zealand (FSANZ) prepared Proposal P1016.

Various foods containing apricot kernels as ingredients were analysed in the survey,

³⁶ <http://www.foodstandards.gov.au/code/Pages/default.aspx>

³⁷ 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.

³⁸ 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.

³⁹ 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: <http://www.foodstandards.gov.au/science/surveillance/Pages/Combined-survey-and-risk-assessment-for-cyanogenic-glycosides.aspx>

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)⁴⁰.

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.⁴¹

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 Laetrile⁴² (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.⁴³

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.

FSANZ was advised by the state/territory jurisdictions (whose role it is to enforce the Code⁴⁴)

⁴⁰ 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.

⁴¹ [Submission from Cancer Council Australia to FSANZ's Proposal P1016 - Hydrocyanic acid in Apricot Kernels & Other Foods](#)

⁴² <http://www.cancertutor.com/laetrile/>

⁴³ <https://www.accc.gov.au/media-release/cancer-treatment-found-to-be-misleading>

⁴⁴ <http://www.foodstandards.gov.au/code/Pages/default.aspx>

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)⁴⁵.
- 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 glycosides⁴⁶.

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.

⁴⁵ 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](#).

⁴⁶ 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 day⁴⁷. 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:

⁴⁷

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

- whole apricots containing raw apricot kernels
- 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 businesses⁴⁸ in 2013⁴⁹, 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 Laetrile⁵⁰ through consumption of raw apricot kernels is effective in the treatment or prevention of cancer.

⁴⁸ 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.

⁴⁹ This information was gathered from a survey sent to 46 businesses in both Australia and New Zealand.

⁵⁰ 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 cancer⁵¹.

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.⁵¹

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.
- 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.

⁵¹

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 occur⁵².

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 \$5,624⁵³ per single stock keeping unit (SKU).⁵⁴

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.

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

⁵² 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.

⁵³ [Cost Schedule for Food Labelling Changes](#) – 2014 PricewaterhouseCoopers Report commissioned by the Department of Health (Australia).

⁵⁴ 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.

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 samples³⁹, 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 poisoning⁵⁵. 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 consequences⁵⁶.

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.⁵¹

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

⁵⁵ Consumer advice website administered by the Cancer Council Australia: <http://www.iheard.com.au/question/eating-apricot-kernels-cure/>

⁵⁶ American Cancer Society - <http://www.cancer.org/>

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 Policy⁵⁷ 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.

⁵⁷ <https://www.accc.gov.au/about-us/australian-competition-consumer-commission/compliance-enforcement-policy>

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 ⁵⁸	Option 2 ⁵⁹	Option 3 ⁶⁰	Option 4 ⁶¹	Option 5 ⁶²
Direct retail sale of raw skin-on apricot kernels as food	Yes	Yes	Yes ⁶³	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

⁵⁸

Option 1: Maintain the status quo

⁵⁹

Option 2: Mandatory labelling of all raw apricot kernels

⁶⁰

Set a maximum level of HCN all raw apricot kernels

⁶¹

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.

⁶²

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.

⁶³

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 oil⁶⁴. 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 explored in this Decision RIS, but the collected information was not sufficient for the detailed

⁶⁴ They have a requirement from their suppliers that Apricot kernel oil is hydrocyanic acid free.

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 therefrom⁶⁵. The revised draft variation would still

⁶⁵ 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

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.

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Available at:

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US Food and Drug Administration - Import Alert 62-01. Available at:

http://www.accessdata.fda.gov/cms_ia/importalert_167.html

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 sources⁶⁶.

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 consumed⁶⁷.
- 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 consumed⁶⁸.

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	

⁶⁶

⁶⁷

⁶⁸

<http://www.ncbi.nlm.nih.gov/pubmed/17079589>
[Sayre and Kaymakcalavu \(1964\)](#)
[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.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/13308a-eng.php>).

Additionally, in 2009, Health Canada published a fact sheet on its Food and Nutrition website about cyanide in bitter apricot kernels (<http://www.hc-sc.gc.ca/fn-an/pubs/securit/2009-apricots-abricots/index-eng.php>).

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)⁶⁹ 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
www.food.gov.uk/news/newsarchive/2006/apr/apricot.

⁶⁹

<http://tna.europarchive.org/20111116080332/cot.food.gov.uk/pdfs/tox-2006-13.pdf>

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
http://www.chp.gov.hk/en/view_content/37324.html.

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 links:

<http://www.foodstandards.gov.au/foodstandards/changingthecode/standardsworkplan.cfm> and
<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1016hydrocy5438.aspx>

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 numbers⁷⁰, 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.

⁷⁰

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.

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

Australia

New Zealand

How many kilograms of apricot kernel products do you import per year?

What type of apricot kernel products do you import? (e.g. dried apricot kernels, apricot kernel oil). And how many kilograms of apricot kernel product do you import?

Apricot kernel product	Quantity imported per year (in kilograms)	Price your business pays for imports \$
Dried apricot kernels with skin-on (unhulled)		
Dried apricot kernels without skin (hulled)		
Apricot kernel oil		
Other foods ⁷¹ (please specify)		

What percentage of your imported dried apricot kernels goes in to further processing for foods derived from apricot kernels⁷²? This includes both processing your business undertakes and processing by other businesses you sell to.

Does your business also sell apricot kernel products directly to consumers?

How many retail businesses do you supply apricot kernel products to?

⁷¹ For example (amaretti biscuits, almond finger biscuits, apricot jams, apricot nectar)
⁷² 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 your business is based.

Australia

New Zealand

What type of apricot kernel products do you produce? (eg. dried apricot kernels, apricot kernel oils) And how many kilograms of each type of apricot kernel products do you produce?

Apricot kernel product	Quantity produced per year (in kilograms)
Dried apricot kernels with skin-on (unhulled)	
Dried apricot kernels without skin (hulled)	
Apricot kernel oil	
Other foods⁷³ (please specify)	

What are the costs your business incurs in producing apricot kernels with skin-on (unhulled) and apricot kernels without skin (hulled)? (e.g. – agricultural costs, harvesting costs, storage costs, processing costs, packaging, labelling, etc.)

Apricot kernel product	Production costs \$
Apricot kernels with skin-on (unhulled)	
Apricot kernels without skin (hulled)	

Does your business sell apricot kernel products directly to consumers?

How many retail businesses do you supply apricot kernel products to?

⁷³

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 2015⁷⁴. 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.



1 Skin-on (unhulled) apricot kernels



2 Skin-off (hulled) apricot kernels

⁷⁴ The Call for Submissions and its supporting documents (including the Consultation RIS) are available from the FSANZ website: <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1016hydrocy5438.aspx>

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 , 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 poisoning in a 26 year old male.</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 http://iheard.com.au/question/eating-apricot-kernels-cure/</p>

Issue	Raised by	FSANZ response
<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>Requested that the prohibition be rejected as people may seek</p>	Brian Sandle	<p>FSANZ has identified a significant acute public health and safety dietary risk</p>

Issue	Raised by	FSANZ response
<p>alternative treatments after conventional has failed. There still needs to be a way in which researchers can access amygdalin for testing.</p>		<p>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 consumer⁷⁵</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>	
<p>Suggested that the CFS Report contains a lot of scientific</p>	<p>Deb Gully</p>	

⁷⁵

Individual consumers did not give FSANZ permission to release their names

Issue	Raised by	FSANZ response
<p>evidence about the theoretical dangers of cyanide poisoning from apricot kernels but very little actual, real life evidence. Supports option 1 (status quo) with option 2 (labelling) as a second preference, although it may penalise manufacturers, retailers or consumers.</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>	Heather Howard	
<p>Opposed to the prohibition as there is evidence that foods containing dietary cyanides are a valuable therapeutic tool.</p>	Ian Gregson	
<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>	Bill Leonard	
<p>Suggests that people should take responsibility for their own choices rather than FSANZ ban foods.</p>	Julie Noakes	
<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 different from “bitter” almonds to avoid any further confusion.</p>	Almond board of Australia and Nuts for Life	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.

Issue	Raised by	FSANZ response
<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>	<p>NZFGC</p>	<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> <p>(i) Prescribing a list of acceptable products requires some guidance to industry and consumers as to when a food that</p>	<p>NSW Food Authority</p>	<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>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. However, have some concerns that the variation, as drafted, will impact on legitimate use of these products:</p>	<p>The Victorian Departments of Health and Human Services and</p>	<p>FSANZ notes and welcomes the suggestion of a more strategic consideration regarding how non-food raw apricots kernels may be sold to consumers.</p> <p>FSANZ undertook a robust RIS which was agreed by OBPR. There was</p>

Issue	Raised by	FSANZ response
<p>(iv) 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>(v) 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>(vi) 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 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</p>	<p>Economic Development, Jobs, Transport and Resources (the Departments)</p>	<p>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>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>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>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 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>

Issue	Raised by	FSANZ response
		<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 http://www.lemke.de/en/produkte/sortiment/persipanmassen.html. 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>

Issue	Raised by	FSANZ response
<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 http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx</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 issues raised by China.