

16 December 2014
[26–14]

Call for submissions – Proposal P1016

Hydrocyanic acid in Apricot Kernels & other Foods

FSANZ has assessed a proposal for the risk management of hydrocyanic acid in apricot kernels and other foods and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 February 2015

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at

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

- SD1 Poisoning incidents from hydrocyanic acid (HCN) in apricot kernels and regulation of HCN in general foods internationally

- SD2 COAG Consultation Regulation Impact Statement – Regulation of cyanogenic glycosides in apricot kernels and other foods

Executive summary

Some plant-based foods contain cyanogenic glycosides which can pose risks to consumers. The toxicity of cyanogenic glycosides and their derivatives depends on the release of hydrocyanic acid (HCN) from plant tissue. This may occur by the action of gut bacteria in animals or humans (at variable rates) after enzyme activity in the gut.

As a result of previous detections of HCN in ready-to-eat cassava chips, FSANZ recognised that a more thorough review of cyanogenic glycosides should be undertaken in order to determine whether there were any public health and safety concerns in a range of other foods. Therefore, the levels of HCN in foods were assessed in a coordinated food survey under the Implementation Sub-Committee 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 from the consumption of foods containing HCN that have been identified in the analysis of the ISFR survey results.

No public health and safety concerns were identified 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, United Kingdom 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.

In order to manage the risks of consumption of raw apricot kernels, FSANZ has prepared a draft variation to the Code. In the interim, while this measure is being considered, updated advice on the maximum amount of raw apricot kernels that can safely be consumed has been provided on the FSANZ website¹.

The draft food regulatory measure prohibits 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 would also apply to any substance derived from raw apricot kernels, with some exceptions as noted below, but does not prevent apricots containing raw apricot kernels from being added to food or offered for sale as a food.

The risk assessment identified a number of foods derived from apricot kernels for which no public health and safety concerns have been identified. Therefore, FSANZ is proposing exemptions from the prohibition for alcoholic beverages, oil, flavourings, stone fruit juices, marzipan, cakes, biscuits and confectionery derived from apricot kernels.

¹ <http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx>

1. Introduction

Some plant-based foods contain cyanogenic glycosides which can pose risks to consumers. Cyanogenic glycosides are naturally occurring sugars that have the cyanide moiety in their structure. The toxicity of cyanogenic glycosides and their derivatives depends on release of hydrocyanic acid (HCN) from plant tissue. This may occur by the action of gut bacteria in humans (at variable rates) following consumption of plants containing cyanogenic glycosides.

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. However, in bitter almonds and 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 Sub-Committee 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.

There were a small number of foods (raw apricot kernels, cassava roots and bread containing linseed) where it was estimated that 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 2.1 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. The Western Australia poisoning incident resulted in a FSANZ initiated national product recall. 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.

² <http://www.foodstandards.gov.au/science/monitoring/surveillance/Pages/Combined-survey-and-risk-assessment-for-cyanogenic-glycosides.aspx> Download the survey for cyanogenic glycosides (pdf 1541kb) | (word 553kb)

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/fsanzwarnsagainstcon5338.aspx>

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 SD2.

Poisoning incidents from consumption of apricot kernels has also been reported in other countries: Canada, United Kingdom and Europe (see SD1).

In countries other than Australia and New Zealand the risk of poisoning incidents has been managed by:

- Advice for consumers on a recommended maximum number of apricot kernels to be consumed per day (United Kingdom and Canada).
- 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.
- Prohibition on sale of apricot kernels as a food since they are regulated as a drug (laetrile (amygdalin)) under import legislation (US).

1.1 The Proposal

FSANZ has 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.

This Proposal 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 edible 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) raw apricot kernels



Hulled (without skin) raw apricot kernels

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.

1.2.2 Hydrocyanic acid in other foods

Levels of HCN 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.

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 currently includes 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. In Standard 1.4.4, 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 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 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.

1.2.3 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 the Proposal

This Proposal was raised 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 incidences in Australia from consumption of raw apricot kernels.

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2. Summary of the assessment

2.1 Risk assessment

The full risk assessment has been conducted as part of the ISFR Coordinated Food Survey Plan (see paragraph 3 in Section 1 of this draft assessment summary, and the full survey report⁷).

While public health and safety issues were identified for acute dietary exposure to apricot kernels (see 2.1.1 below), there were no public health and safety issues identified in relation to the estimates of chronic dietary exposure to HCN from any plant-based food for the Australian and New Zealand populations, based on the survey data available.

For cassava roots, there is 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 are 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 are 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 concludes that there is no appreciable health and safety risk from consumption of these foods for consumers.

2.1.1 Raw apricot kernels

The risk assessment has 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.

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 was conducted for raw apricot kernels for adults only (see Table 1). As no nutrition survey 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). Estimated dietary exposures ranged between 910-940% ARfD for kernels with skin and 140-150% ARfD for kernels without skin. Using the maximum HCN levels in raw apricot kernels found in the ISFR survey (2,820 mg HCN/kg), dietary exposure from 4 kernels slightly exceeded the ARfD for kernels with skin (110-120%), but not for kernels without skin (20% ARfD).

⁷ <http://www.foodstandards.gov.au/science/monitoring/surveillance/Pages/Combined-survey-and-risk-assessment-for-cyanogenic-glycosides.aspx> Download the survey for cyanogenic glycosides (pdf 1541kb) | (word 553kb)

Table 1: Estimated acute dietary exposures to total HCN for Australian and New Zealand population groups as a per cent 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).

^a Survey 2, EU method.

^b Survey 1.

^c Survey 3, sweet cassava only.

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 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 estimation of the maximum number of raw apricot kernels that could be consumed before exceeding the ARfD was also undertaken for this product using maximum mean 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 and children could not even consume 1 kernel/day before the ARfD is exceeded. 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 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 recommendation⁸ 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 kernel/day, it is very likely that HCN consumption amounts would exceed the ARfD.

2.1.2 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) and were found to not pose a public health and safety risk.

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 will not 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).

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).

2.2 Risk management

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

Risk management measures are needed for raw apricot kernels and for any substance derived from raw apricot kernels which is not further processed (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).

In order to manage the risk of consumption from raw apricot kernels, FSANZ considered the following non-regulatory and regulatory options:

- Option 1: Maintain the status quo and abandon the Proposal. FSANZ would rely on the current website advice which describes the number of raw apricot kernels that can be safely consumed per day.
- Option 2: Prepare draft variations to apply mandatory labelling requirements of both unhulled (skin on) and hulled (skin off) raw apricot kernels.
- Option 3: Prepare draft variations to set a maximum limit in Standard 1.4.1 for unhulled (skin on) and hulled (skin off) raw apricot kernels.

⁸<http://www.foodstandards.gov.au/consumer/safety/Pages/Apricot-kernels-raw.aspx>

- Option 4: Prepare draft variations to include a prohibition on the sale of unhulled (skin on) raw apricot kernels only in Standard 1.4.4 with exemptions for raw apricot kernel-derived foods that are safe for consumption⁹. In parallel, manufacturers would be required to provide advice for consumers on the maximum amount of hulled (skin off) raw apricot kernels that could safely be consumed on their product labels.
- Option 5: Prepare draft variations to include a prohibition on the sale of unhulled (skin on) and hulled (skin off) raw apricot kernels in Standard 1.4.4 with exemptions for apricot kernel-derived foods that are safe for consumption

FSANZ considers that maintaining the status quo (a non-regulatory approach) or other regulatory options (1, 2, 3 and 4) are not appropriate options for the following reasons:

- A significant potential harm exists from high dietary levels of HCN particularly for children.
- Options 1, 2, 3 and 4 are unlikely to adequately ensure public safety due to the uncertainty surrounding the absolute maximum levels of HCN that could potentially be present in raw unhulled or hulled apricot kernels.
- Option 1 – Effectiveness of website advice and labelling is likely to be limited, as it is dependent on consumers seeking and noticing and taking account of this information.
- Option 3 – 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 in Option 5.
- Based on the experience from previous poisonings and the latest poisoning incident in Western Australia, FSANZ concludes that options 1, 2, 3 and 4 would not adequately protect public health and safety.

The risk assessment on a number of foods derived from apricot kernels which were surveyed indicated there is no potential risk arising from their consumption. The data from the ISFR survey shows that the levels of HCN in apricot kernel-derived foods (amaretti biscuits, almond finger biscuits), apricot jams and apricot nectar do not present public health and safety concerns. Levels of HCN in apricot oil do not pose a risk. There are also other foods derived from apricot kernels (e.g. amaretto liquor)¹⁰ 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 Code¹¹.

FSANZ is calling for information on any other food products that are being sold and produced which use apricot kernels as an ingredient including details of how such foods are produced or processed.

2.2.1 Proposed risk management option

Prior to public consultation, FSANZ considers that overall Option 5, 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) is likely to have the greatest net benefit and is therefore the preferred option.

⁹ This option allows the continued sale of hulled (skin off) apricot kernels.

¹⁰ Amaretto is a sweet, almond-flavoured, Italian liqueur. It is made from a base of apricot kernels or almonds, sometimes both

¹¹ Confectionery, stone fruit juices, marzipan and alcoholic beverages

Other measures are unlikely to be effective at managing the risk to public health and safety from consumption of raw apricot kernels and unprocessed products derived from them.

The determination that this option is likely to have the greatest net benefit is based on qualitative analysis due to difficulty obtaining quantitative information from industry. Based on the current information FSANZ has to date, the potential costs of the proposed measure will not exceed the value of the anticipated direct and indirect benefits to the public. The Regulatory Impact Statement (RIS) concludes that the proposed measure is the most cost-effective response to the regulatory issue that has been identified, based on a qualitative evaluation (Refer to SD2).

This prohibition relates only to food use of apricot kernels and does not extend to a prohibition on use of foods derived from apricot kernels which does not pose health risks (e.g. as an ingredient in other foods).

In summary, the decision 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:

- 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.

2.3 Decision

It is proposed to vary Standard 1.4.4 to prohibit raw apricot kernels or substances derived from raw apricot kernels from being intentionally added to food or offered for sale as food. The prohibition would also apply to any substance derived from raw apricot kernels which is not further processed (i.e. whole raw kernels or kernels that have been ground, milled, cracked or chopped).

The prohibition does not prevent apricots containing raw apricot kernels from being added to food or offered for sale as a food. Furthermore, it is proposed to exempt the following foods from the prohibition:

- alcoholic beverages
- oil
- flavourings
- stone fruit juices
- marzipan
- cakes
- biscuits
- confectionery.

2.4 Risk communication

2.4.1 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.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on draft variations to the Code.

FSANZ now invites further comment from industry, consumers and other stakeholders on the proposed regulatory measure for managing the risks associated with HCN in apricot kernels, including on the potential impacts and costs outlined in the cost benefit analysis and contained in the consultation RIS at SD2. Comments are specifically requested from the apricot kernel industry on the questions raised in the consultation RIS (SD2). Additional information in response to this Call for Submissions may enable FSANZ to conduct a more quantitative analysis for the Decision RIS, depending on the quality of data/information received from affected parties. This could potentially result in FSANZ arriving at a different preferred option.

All public comments received are reviewed and considered before approval of a variation to the Code by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

A communication strategy has been developed for this Proposal. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified via email about the availability of reports for public comment. Individuals and organisations making submissions on this Proposal will be notified at each stage of assessment.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (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 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 unhulled (with skin) and hulled (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) 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, 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 has been made to enable other WTO members to comment on the proposed amendments.

2.5 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:

2.5.1 Section 59

2.5.1.1 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.

A consultation RIS accompanies this call for submissions and assessment summary (SD2). It provides a qualitative cost benefit analysis using the information currently available to FSANZ. Additional information from the consultation may enable FSANZ to undertake a more quantitative based impact analysis of the proposed options in the Decision RIS. This depends however on the quality of data/information received from affected parties. The information/data received as a result of this consultation may result in FSANZ arriving at a different preferred option.

A range of specific questions are posed in the Consultation RIS (ID No. 16574) to assist in the development of a Decision RIS and further consideration by FSANZ.

In addition to the call for submissions on the draft variation, FSANZ is seeking comment on the Consultation RIS at SD2 and responses to a number of specific questions.

The RIS and preferred option for this Proposal was approved by the Office of Best Practice Regulation (OBPR) in September 2014.

For further information and specific questions on which FSANZ is seeking comment, refer to SD2.

2.5.1.2 Other measures

For the reasons described in the Consultation RIS, FSANZ is satisfied that no other measures would be more cost-effective than a food regulatory measure.

2.5.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards. However, the proposed draft variations will apply in both Australia and New Zealand.

2.5.1.4 Any other relevant matters

Some people consume raw apricot kernels because of claims of health benefits (e.g. prevention or curing of cancer), but may not be aware of the risks of HCN poisoning. There are a range of websites that are marketing these products.

2.6 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.1 Protection of public health and safety

In regard to raw, unhulled and hulled apricot kernels, FSANZ has concluded that a prohibition would support the primary objective of protecting public health and safety by lowering the risk of future poisoning incidences in Australia and New Zealand.

2.6.2 *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 is considered in the Consultation RIS. However, FSANZ did not consider that labelling of apricot kernels was an appropriate risk management measure to mitigate a potentially serious public health risk for the general community where public awareness of the risk is low.

2.6.3 *The prevention of misleading or deceptive conduct*

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

2.7 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 the consumption of HCN in raw apricot kernels. This risk assessment has considered all 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**

The proposed variation to prohibit the sale of raw apricot kernels is not consistent with any international legislation, as there are no standards for raw, unhulled or hulled apricot kernels in other countries. However FSANZ considers taking an independent approach to this issue is justified on the grounds of protection of public health and safety

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

Australia and New Zealand's reputation as a producer of safe food is an important factor in being regarded as an internationally reputable food industry. However, there are no relevant international standards and amending the Code to prohibit the sale of raw apricot kernels both unhulled (with skin), hulled (without skin) and any substance derived from raw apricot kernels which is not processed further may have an effect on international trade. Therefore, FSANZ has made a notification to the WTO in order to understand these impacts on the apricot kernel industry. In addition, the Consultation RIS has specific questions for importers of apricot kernels in order to further understand the cost impacts on industry.

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

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

- **any written policy guidelines formulated by the Ministerial Council**¹²

No Policy Guideline is applicable.

3. Draft variation

The draft variation is at Attachment A. The variation is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

3.1 Transitional arrangements

The draft variation will commence on the date of gazettal. FSANZ considers that no transitional arrangements are required for this Proposal on the basis that the proposed amendments are required to reduce identified public health and safety concerns from consumption of raw apricot kernels. Relevant parties have been kept informed of this proposal and can make appropriate commercial decisions to minimise the cost.

3.1.1 Transitional arrangements for Code Revision

FSANZ has reviewed the Code in order to improve its clarity and legal efficacy through Proposal P1025 – details of which are on the FSANZ website¹³. The FSANZ Board has approved draft variations arising from this Proposal and notified that decision to Ministers. If no review is requested by Ministers, it is expected that the new Code will commence on 1 March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A.

4. References

Akil M et al (2013) Acute cyanide intoxication due to apricot seed ingestion. *J Emerg Med.* 44: 285-6

Akyildiz BN et al (2010) Cyanide poisoning caused by ingestion of apricot seeds. *Ann Trop Paediatr.* 30:39-43.

Atkinson K. (2006). Apricot kernels carry risk of cyanide poisoning. Accessed at: http://www.nzherald.co.nz/organisation/story.cfm?o_id=324&objectid=10379786

Cigolini D et al (2011) Hydroxocobalamin treatment of acute cyanide poisoning from apricot kernels. *Emerg Med J.* 28: 804-5.

Codex Standard for Sweet Cassava (2005). *Codex Stan*, 238-2003.

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

FSANZ (2011) FSANZ warns against consuming raw apricot kernels. 4 November 2011. <http://www.foodstandards.gov.au/media/Pages/mediareleases/mediareleases2011/fsanzwarnsagainstcon5338.aspx>

Gandhi VM et al (1997) Safety evaluation of wild apricot oil. *Food Chem Toxicol.* 35:583-7.

¹² Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

¹³ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

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.

Holzbecher MD, Moss MA, Ellenberger HA (1984) The cyanide content of laetrile preparations, apricot, peach and apple seeds. *Journal of Toxicology. Clinical Toxicology* 22 (4): 341-347.

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

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

Suchard et al (1998) Acute cyanide toxicity caused by apricot kernel ingestion. *Ann Emerg Med*. 32:742-4

USFDA

<http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm091048.htm>

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – 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 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 B – Draft 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.

FSANZ 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.

2. Purpose

The Authority has prepared a draft variation to impose a prohibition on the sale of raw apricot kernels (unhulled and hulled) in Standard 1.4.4 with an exemption for apricot kernel-derived foods that are safe for consumption. This is due to the risk to public health and safety of the continued sale of raw apricot kernels (unhulled and hulled).

However, the draft variation also exempts specific foods deriving from apricot kernels from that prohibition on the basis that these foods are safe for consumption.

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 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (which includes the assessment and the draft variation) will be released for a six-week consultation period.

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.

6. Variation

The draft variation commences on the date of gazettal and inserts new clause 3 into Standard 1.4.4 Prohibited And Restricted Plants And Fungi.

Proposed subclause 3(1) provides a definition of the term 'raw apricot kernels' for the purposes of clause 3.

Proposed subclause 3(2) prohibits raw apricot kernels or substances derived from raw apricot kernels from being intentionally added to food or offered for sale as food.

Proposed subclause 3(3) exempts the following foods from the above prohibition:

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

Proposed subclause 3(4) states that the prohibition in subclause 3(2) does not prevent apricots containing raw apricot kernels from being added to food or offered for sale as a food.

Proposed subclause 3(5) 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 to Standard 1.4.4 made by the draft variation.