

23 March 2017
[08–17]

Approval report – Proposal P1026

Lupin as an Allergen

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to consider options to regulate food containing lupin as a food allergen.

On 16 June 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 14 submissions.

FSANZ approved the draft variation on 9 March 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 22 March 2017.

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

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Supporting document

The [risk assessment](#)¹ which informed the assessment of this Proposal is available on the FSANZ website:

SD1 Risk Assessment (at Approval)

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1026lupinas5830.aspx>

Executive summary

FSANZ prepared this Proposal to consider the population health significance of lupin as a new food allergen in Australia and New Zealand and to develop appropriate risk management measures as required.

The assessment has considered lupin in the form of lupin seeds (also known as kernels), which can be consumed whole (either raw or after preparation), plus all products derived from lupin seeds whenever it is present in a food. Throughout this assessment summary the term “lupin and lupin-derived products” refers to any edible form of the lupin.

The nutritional properties of lupin are being recognised and the use of lupin in foods is increasing around the world. In Australia, various locally made and imported lupin-containing food products are available to consumers and a wide range of lupin-derived ingredients are in various stages of commercial development. For many existing uses of lupin in food its presence as an ingredient is declared in ingredient labelling on food labels. However, some current and future applications, such as use in very small quantities, used to produce food additives and processing aids, or unpackaged and restaurant foods, may not be captured by these labelling requirements, potentially meaning the presence of lupin ingredients in food is not always declared.

Lupin allergy was first reported in the medical literature in Australia in 2004 and severe allergic reactions, including anaphylaxis, to lupin and lupin-containing food products have been reported. Allergic reactions to lupin, based on EU and Australian evidence, fulfil the international criteria provided by the World Health Organization for identifying new food allergens of public health significance.

The prevalence of lupin allergy in the general population in Australia and New Zealand is unknown. However, the number of people at risk may be estimated from the prevalence of peanut allergy, based on the known immunological cross-reactivity between peanut and lupin antigens. Lupin allergenicity may also be associated with cross-reactivity with other legumes, such as soy.

Lupin has been recognised as a significant allergen in the European Union food regulations since 2007 and requires mandatory declaration in foods.

The decision to identify lupin as an allergen by including it in section 1.2.3—4 of the Code means it is included in mandatory labelling requirements therefore providing additional information to consumers who are allergic to lupin. The amendment occurs on gazettal with a 12 month transition period.

Risk management considerations arising from submissions included mandatory versus voluntary approaches, labelling, managing the inadvertent presence of lupin, length of transition period and analysis of lupin in foods. These issues were considered, and in conjunction with a cost benefit analysis, supported an amendment to the *Australia New Zealand Food Standards Code*. The approved draft variation at Attachment A is proposed to take effect on gazettal, with a 12-month transition period. A Decision Regulatory Impact Statement approved by the Office of Best Practice Regulation is at Attachment D.

Both public and targeted consultation had been conducted in order to inform this process. Expert advice was received on the risk assessment from the Food Allergy and Intolerance Advisory Group convened by FSANZ. Members of the World Trade Organization were notified and comment received from the United States of America which pointed out a typographical error which was corrected.

1 Introduction

1.1 The Proposal

FSANZ prepared this Proposal to:

- evaluate the population health significance of lupin as a new food allergen in Australia and New Zealand against international criteria for new allergens, including the potential for cross-reactivity with other legume-based food allergens such as peanut and soy
- develop appropriate risk management strategies to manage the identified risks, including consideration of a need for food regulatory measures in the Australia New Zealand Food Standards Code (the Code).

The assessment has considered lupin in the form of lupin seeds (also known as kernels), which can be consumed whole (either raw or after preparation, such as in brine), plus all products derived from lupin seeds/kernels e.g. flour, meal, hulls, bran, lupin grits and oil. Lupin, whenever it is present in a food as an ingredient, ingredient of a compound ingredient, food additive or processing aid (including when used as an ingredient or component of these), is also included as part of the consideration of the Proposal.

Throughout this assessment summary, the term “lupin and lupin-derived products” refers to any edible form of the lupin seed/kernel.

1.2 Current standards

1.2.1 Lupin and natural contaminants

The only permissions in the *Australia New Zealand Food Standards Code* (Code) which are specific to lupin and lupin products are in Schedule 19 – Maximum levels of contaminants and natural toxins.

Section S19—5 sets maximum levels for phomopsins in lupin seeds and products of lupin seeds, whilst section S19—6 sets limits for the natural toxins “Lupin alkaloids” in lupin flour, lupin kernel flour, lupin kernel meal and lupin hulls.

Neither of these requirements is affected by FSANZ’s approved draft variation to require the mandatory declaration of lupin and lupin-derived products in food.

1.2.2 Lupin and mandatory declaration of food allergens

Section 1.2.3—4 in Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations lists certain foods or substances which must be declared when present in a food. Lupin is not currently listed as a food allergen requiring declaration.

The foods, or products of these foods or substances listed, must be declared when present as an ingredient, an ingredient of a compound ingredient, or as a food additive or processing aid (including when used as an ingredient or component of these).

In accordance with Standard 1.2.1 – Requirements to have labels or otherwise provide information, the declaration required by section 1.2.3—4 must be provided on the label of packaged food, or where a food is not required to bear a label (e.g. when the food is unpackaged or is made and packaged on the premises), the declaration must be displayed in connection with the display of the food, or provided to the purchaser on request.

1.2.3 Lupin and ingredient labelling

The use of lupin or lupin-derived products as ingredients in food is subject to the existing ingredient labelling requirements in Standard 1.2.4 – Information requirements – statement of ingredients. This Standard requires most packaged foods to declare each ingredient in a statement of ingredients using the common name of the ingredient, or a name that describes the true nature of the ingredient, or a generic name (listed in Schedule 10). However, food additives must be declared by their class name (e.g. ‘thickener’) followed by their name or code number. The specific source of a food additive (e.g. lupin) is not required to be declared, unless derived from a food allergen requiring declaration in section 1.2.3—4.

Some exemptions apply to listing ingredients in a statement of ingredients; for example, processing aids, and the ingredients of a compound ingredient which makes up less than 5% of the food for sale are not required to be listed (unless listed as requiring declaration in section 1.2.3—4 or if used as a food additive performing a technological function). As such, lupin ingredients in these situations would not be required to be listed. There are also instances where a statement of ingredients is not required to be provided, for example, foods in small packages (surface area less than 100 cm²), and foods that are not required to bear a label (e.g. unpackaged foods or foods that are made and packaged on the premises such as in a bakery or restaurant).

In regard to the use of generic names in a statement of ingredients, Schedule 10 – Generic names of ingredients and conditions for their use permits the generic name “vegetable oil” to be used with some conditions. This includes the condition to declare the specific source name of the oil if it is sourced from peanut, sesame or soybeans (with some exceptions) i.e. known food allergens. Lupin is not currently included in this condition. Therefore oil sourced from lupin can currently use the generic name “vegetable oil” in the statement of ingredients, rather than declare the specific source name e.g. “lupin”.

1.2.4 Regulation of lupin in food in other countries

1.2.4.1 Europe

In Europe (since 2007), where lupin and its products are present in food, it is mandatory to inform consumers of their presence due to their allergic potential. This requirement was implemented in Commission Directive 2006/142/EC² which required the addition of ‘Lupin and products thereof’ to be added to the lists of allergens in Annex IIIa of Directive 2000/13/EC³ requiring mandatory labelling.

Directive 2000/13/EC has since been repealed by Regulation (EU) No 1169/2011⁴. Annex II of Regulation (EU) No 1169/2011 is a list of substances or products causing allergies or intolerances, which includes lupin and products thereof.

² Commission Directive 2006/142/EC, of 22 December 2006 amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs.

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1486355689351&uri=CELEX:32006L0142>

Accessed 6 February 2017.

³ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1486356880342&uri=CELEX:32011R1169> Accessed 6 February 2017

⁴ Regulation (EU) No 1169/2011 of the European Parliament and the Council of 25 October 2011 on the provision of food information to consumers. <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1486356554697&uri=CELEX:32011R1169> Accessed 6 February 2017.

Paragraph (24) and Article 9(1)(c) of the EU regulation require information on any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II used in the manufacture or preparation of a food and still present in the finished product, even in an altered form, to be available to the consumer.

1.2.4.2 Other countries

FSANZ has not identified any specific regulatory standards in other countries regarding requirements to label lupin or lupin-derived products on food labels as mandatory allergens.

The [United States Food and Drug Administration](#) (USFDA) acknowledges⁵ that some people, including those allergic to peanuts, may have allergic reactions after eating lupin or foods containing ingredients from lupin. However, the [Food and Allergen Labeling and Consumer Protection Act](#)⁶ currently does not require special allergen labelling for lupin or lupin-derived ingredients, as they are not classed as “major” food allergens.

The USFDA labelling rules require ingredients to be declared by name in the ingredients list on the food label, unless they meet the exemption requirements due to being present in “incidental” amounts in a finished food. If an ingredient is present at an incidental amount and has no functional or technical effect in the finished product, then it need not be declared on the label.

1.3 Reasons for preparing the Proposal

This Proposal was prepared to consider the risk management of potential health or safety issues arising from foods containing lupin as assessed as part of an internal FSANZ risk assessment on lupin as a food allergen (FSANZ, 2010).

In October 2006, the then Australia and New Zealand Food Regulation Ministerial Council (now known as the Australia and New Zealand Ministerial Forum on Food Regulation (Forum)) requested FSANZ to review the regulatory management of food allergens. In December 2010, FSANZ released the report of this review (FSANZ, 2010). One of the recommendations of the report was to develop a proposal to assess whether lupin and lupin-derived products should be included in the list of allergens requiring mandatory declaration in Standard 1.2.3.

The 2010 FSANZ Report⁷ states that *the purpose of the mandatory declaration list in the Code is to prioritise the regulatory management of food allergens*. Therefore, the guiding principle is that inclusion on the list should be determined by the public health significance of the food allergen of concern. To help determine whether lupin and lupin-derived products should be included in Standard 1.2.3, the FSANZ report listed the data requirements to allow an evaluation of the population health significance of possible new allergens. This approach is consistent with international criteria and relevant scientific information; the risk assessment procedure undertaken as part of this Proposal used these identified data requirements.

⁵<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm410111.htm>. Accessed 6 February 2017.

⁶<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064880.htm>. Accessed 6 February 2017.

⁷<http://www.foodstandards.gov.au/consumer/foodallergies/review/documents/Review%20of%20the%20Regulatory%20Management%20of%20Food%20Allergens-FSANZ%20Dec%202010.pdf>

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

There were fourteen submitters to Proposal P1026. Key issues raised are identified in Table 1: Summary of Issues below along with the FSANZ response. The issues raised include, mandatory versus voluntary approaches, labelling considerations, transition period, analytical issues and inadvertent presence of lupin.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Labelling exemptions for highly refined lupin products – consistent with recent allergen labelling exemption granted under P1031, consideration should be given to lupin products that have been degummed, neutralised, bleached and deodorised	Allergen Bureau	Exemptions for highly refined lupin products have not been considered in the scope of this project. FSANZ is not aware of suitable evidence for exempting such products at this point in time.
Include a clarification statement in the Approval Report to advise that co-mingling of grains (including Lupin) does not trigger mandatory labelling, but manufacturers should utilise a precautionary labelling system, such as that provided by VITAL	Allergen Bureau	The presence of lupin as an ingredient, ingredient of a compound ingredient, food additive or processing aid (or an ingredient or components of these), will need to be declared under the mandatory requirements. Voluntary precautionary statements made by a food manufacturer are not generally regulated by the Code. Food manufacturers will need to decide whether to use a precautionary labelling system such as VITAL.
Analytical sensitivity – the use of two lupin assays with different cross-reactivity profiles may be needed to avoid false positives eg with soy and chickpea	Allergen Bureau	See section 2.3.3. ELISA kits are available that will detect lupin. FSANZ acknowledges that some commercially available kits may vary with reactivity to different lupin species and cross-reactivities to other legumes. However, the onus remains on analytical laboratories to validate the kits with the food matrix being analysed. FSANZ understands this is standard industry practice.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The Approval Report should note that manufacturers who apply the AFGC Best Practice Allergen Labelling Guidelines will need to change their labels.</p>	<p>Allergen Bureau</p>	<p>Noted</p>
<p>Some concerns that requirement to label lupin may undermine the commercial viability of a newly developing industry.</p>	<p>Grains Industry Association of Western Australia</p>	<p>Evidence available to FSANZ is that packaged products using lupin or lupin products as ingredients are already declaring lupin in the ingredient list to meet the requirements of Standard 1.2.4 (statement of ingredients). FSANZ is also unaware of any evidence demonstrating commercial disadvantage to the products as a result of this. The variation serves to address comprehensively the presence of lupin when used in food additives, compound ingredients etc and unlabelled foods. FSANZ considers the net benefits of this approach outweigh the cost and any commercial disadvantage brought about by more comprehensive labelling. See section 2.4 below.</p>
<p>A&AA remains concerned by FSANZ's priorities in addressing shortcomings of standard 1.2.3—4, which in many cases remain unresolved.</p> <p>A&AA strongly encourages FSANZ to communicate directly with the peak medical body, the Australasian Society of Clinical Immunology and Allergy at the outset of new projects in order to prioritise the magnitude of the problem, compared with other food allergen labelling issues that need attention.</p> <p>Whilst there was some discussion five or more years ago on the possible increase in individuals with lupin allergy because of potential cross reactivity in those with peanut allergy, anecdotally this does not seem to have become apparent.</p>	<p>Allergy & Anaphylaxis Australia</p>	<p>Noted.</p> <p>FSANZ considers the focus on lupins at this time to be appropriate. See section 2.2.</p> <p>Broader allergen labelling issues are being addressed by FSANZ as part of Proposal P1044.</p> <p>FSANZ sought the advice of its Food Allergy and Intolerance Advisory Group, whose membership includes expert clinicians from Australia and New Zealand. Organisations such as A&AA and the Australasian Society of Clinical Immunology and Allergy, and the Allergen Collaboration are also able to make their views and any concerns known to FSANZ at any time.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>That said, now that FSANZ has spent years and resources investigating the lupin issue, it would seem ludicrous to not include lupin, which is easily hidden in baked goods, as a major allergen.</p>		
<p>Due to standard sampling and delivery procedures GTA members cannot guarantee grain sold for domestic consumption is totally free of lupin seed or lupin seed material and it is uneconomic for all grain to be guaranteed as such. GTA requests no mandatory labelling unless lupin is used as an ingredient, food additive or processing aid.</p>	<p>Grain Trade Australia (GTA)</p>	<p>Mandatory labelling requirements will apply when lupin is present in food as an ingredient, ingredient of a compound ingredient, food additive or processing aid (or an ingredient or component of these).</p> <p>However, where there is uncertainty regarding the absence of lupin in food products or grain supplies, it will be up to food processors and manufacturers to manage the risk accordingly.</p> <p>FSANZ also understands from businesses the need to assure niche markets afforded by the use of lupin (such as gluten free) will drive suitably rigorous specifications for ingredient supplies.</p>
<p>Has consideration been given to honey derived from lupin, and possible issues of allergenicity arising from this.</p>	<p>New Zealand Ministry for Primary Industries (NZ MPI)</p>	<p>FSANZ is unaware of any published literature demonstrating the presence of the allergenic protein in pollen, or reports of incidences of food allergy attributed to consumption of honey derived from lupins.</p> <p>To establish whether or not the honey bees have collected pollen from lupin flowers would require sophisticated analysis that cannot be performed on a routine basis.</p> <p>Furthermore FSANZ notes that to date reports of incidences of lupin allergy have arisen from the consumption of foods derived from lupin seeds rather than honey, and there are no case reports of clinical reactions to ingestion of trace amounts of lupin.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Suggest self-revocation clauses for transitional arrangements so that after transition these (i.e. clause 2.2) no longer appear in the Code. If this is addressed by other means this should be noted in the Approval Report</p>	<p>NZ MPI</p>	<p>The FSANZ Act provides for Minor Procedure Proposals as a means to remove Code provisions that have ceased to have effect. Reliance on this expedited procedure enables simpler and clearer provisions and requirements, particularly for stakeholders. The intent is that the Code will be amended to remove sections 1.2.3—1A and S10—1A after they cease to have effect (i.e. once the prescribed transitional period expires). This will occur by means of a code maintenance proposal.</p>
<p>Association of Analytical Communities is developing a reference method for lupin. Australian laboratories are not currently NATA accredited for lupin testing. It is unknown whether non-European importers have facilities for lupin testing.</p>	<p>New South Wales Food Authority (NSWFA)</p>	<p>Advice from analytical laboratories confirms that ELISA kits are available to detect lupin (see section 2.3.4)</p> <p>Development of NATA accreditation is demand driven. NATA accreditation will increase with the need for lupin analysis.</p>
<p>Costs to industry and government have been inadequately addressed and are likely to be underestimated</p>	<p>NSWFA</p>	<p>FSANZ does not accept that such costs have been inadequately addressed or underestimated in its assessment. See in this regard, section 2.4 and the Decision RIS at Attachment C. The Decision RIS was subject to independent assessment by the Office of Best Practice Regulation.</p> <p>FSANZ adopted a cautious approach in estimating cost. For example, upfront costs of implementation to government are estimated to be around \$28,400 per jurisdiction - \$20,000 for staff training and \$8,400 for integrating new regulation into their administrative procedures. However such costs may well be less given that the change involves adding one additional allergen to an existing allergen management framework rather than implementing a new procedure. Due regard was also given to the increased need for and cost of food testing and analysis for compliance purposes.</p> <p>The cost to government and industry of this measure was taken into account by FSANZ.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
		<p>However, FSANZ considers that these costs are outweighed by the benefits to consumers due to reduced number of adverse health reactions associated with consumption of lupin and lupin products and reduced financial and wellbeing costs to lupin sensitive individuals and to governments including state and territory health systems..</p> <p>The estimated financial cost⁸ of food allergy is around \$2,369 per person per annum. If the value of lost wellbeing is included, the cost economic⁹ is \$8,920 per person per annum. Individuals with allergies bear 48% of the financial costs, and their families and friends bear a further 1%. Federal government bears 32% of the financial costs; State and Territory governments bear around 5% of the costs, with the remaining 13% borne by others in society (including employers). If the burden of disease (the economic cost of disability and premature death) is included, individuals bear 86% of the costs.</p>
<p>Concerned re regulation being implemented in the context of lack of data and a not overly significant health and safety impact. Supports Option 2¹⁰ for New Zealand’s purposes but recognises need for trans-Tasman consistency. Thereby, supports adoption of Option 2 only, or Options 2 and 3 with the implementation of Option 3 (regulation) in place for adoption at a future date, based on evaluation of the uptake by industry, and lupin allergen incidence.</p>	<p>New Zealand Food and Grocery Council</p>	<p>For the reasons outlined in this report, FSANZ considers Option 3 and the approved variation to be warranted. The severity and potential risk of allergenic reactions requires a proportionate risk management approach. See sections 2.2., 2.3, 2.4., Attachment C and SD1.</p>

⁸ Total financial costs comprise both direct medical costs and the indirect costs of lost productivity and the deadweight costs of additional taxation

⁹ Total economic costs comprise total financial costs plus the human welfare costs of pain and suffering caused by allergies and raised risk of premature death.

¹⁰ Option 1 – status quo, Option 2 – voluntary measures, Option 3 – regulatory approach

Issue	Raised by	FSANZ response (including any amendments to drafting)
Industry should be encouraged to develop a Receivables Standard (RS) for lupin for human consumption.	Victorian Departments of Health & Human Services; Development & Economic Development, Jobs, Transport and Resources (Vic Govt)	Noted, however outside FSANZ area of responsibility. Industry demand for superior specifications for lupin grains to be used in niche market food products will drive appropriate Receivables Standards
Advice is sought on how lupin can be tested for compliance purposes	Vic Govt	Further detail provided in section 2.3.4.
There is an error in the second sentence at the top of page 6. The US FDA does NOT require any special allergen labelling for lupin or lupin-derived ingredient	United States Food and Drug Administration	Noted, corrected in Approval Report
Transition period - should be extended from 12 months to 18 or 24 months. Manufacturers require additional time to gather information on potential issues of cross-contamination.	Australian Food and Grocery Council (18 months) Food and Beverages Importers Association (18 months) Grains and Legumes Nutrition Council (18 months) Sanitarium Health & Wellbeing (24 months)	Not accepted. FSANZ considers it inappropriate to extend the 12-month transition period given the matter at hand is an allergen.
No issues of concern raised	WA Department of Food and Agriculture	

Further discussion on issues raised is provided in the section below.

2.2 Risk assessment

Lupin is a legume increasingly used in food around the world. The nutritional properties of lupin are being recognised and technological applications are extending the use of lupin in food. In Australia, various locally made and imported lupin-containing food products are available to consumers. Lupin bran and flour are used in staple foods, such as bread and pasta, and confectionery. Also, a wide range of lupin-derived ingredients are in various stages of commercial development. While many existing uses of lupin in food are declared in ingredient labelling on food labels, some current and future applications may not be captured by these labelling requirements, potentially meaning the presence of lupin ingredients in food is not always declared to consumers.

In Europe, lupin allergy is well documented in the medical literature including case reports of severe allergic reactions to lupin in a range of food products, and clinical studies using double blind placebo-controlled food challenges (DBPCFC). Lupin has been recognised as a significant allergen in the European Union food regulations since 2007.

Cases of lupin allergy in Australia were first reported in the medical literature in 2004. Severe allergic reactions, including anaphylaxis, to lupin and lupin-containing food products have been reported in South Australia, Western Australia and the Australian Capital Territory. A Lupin Anaphylaxis Register established by Dr W Smith at the Royal Adelaide Hospital in 2004 contains 14 well-documented cases of lupin-induced anaphylaxis in Australia. This register is no longer updated. In addition to these 14 cases, there have also been reports of at least ten individuals in Western Australia being allergic to ingested lupin. FSANZ is not aware of any clinically-confirmed incidences of lupin allergy in New Zealand.

Australia and New Zealand have among the highest prevalence of allergic disorders in the developed world. The true prevalence of various food allergies, including lupin, in the population is uncertain. However, in view of the known immunological cross-reactivity between peanut and lupin antigens the number of people 'at risk' may be estimated from the prevalence of peanut allergies in Australia and New Zealand. If we assume 1.1% of the population have peanut allergy (the mid-point of the range of prevalence estimates), then that would equate to around 250,000 individuals in Australia and around 50,000 in New Zealand who are peanut allergic and therefore may cross-react to lupin. This estimate does not take into account other individuals who are allergic to lupin-specific proteins or whose allergy to lupin is associated with cross-reactivity with other legumes, such as soy.

The rate of lupin sensitisation will be higher than that of lupin allergy, as sensitisation precedes allergy. As a result of the potential progression from sensitisation to allergy, sensitisation can be used as a risk marker for allergy, although not all sensitised individuals will progress to an allergic state. The estimated rate of lupin sensitisation among patients in Australia who respond to a range of foods by the skin prick test is reported to be 4% in the <1 year age group and up to 25% in the >15 year age group. Lupin challenge studies in patients with known peanut allergy show that 25% of lupin-sensitised children and 41% of adults reacted to lupin. These results suggest under-reporting of lupin allergy in Australia possibly due to limited testing and dietary exposure.

This information has been used to evaluate the significance of lupin against international criteria for identifying food allergens of public health significance (original criteria WHO 2000; revised criteria Björkstén et al 2008 and van Bilsen et al 2011). The outcome of this assessment is that, in Australia, lupin and lupin products represent a significant new allergen that presents a risk to allergic consumers.

Although the presence of lupin in food is currently limited in both Australia and New Zealand, it is likely to increase in the next few years. This would be expected to result in higher dietary exposure to lupin which could result in a greater number of susceptible individuals exhibiting lupin allergy.

The Risk Assessment (at Approval) is provided as SD1, noting it has undergone minor revision to improve the wording on undeclared lupins. There has been no change to the risk assessment itself.

2.3 Risk management

2.3.1 Mandatory versus voluntary measures

Allergies pose severe and life threatening reactions. Currently there is no cure for food allergies.

Strict avoidance of food allergens and early recognition and management of allergic reactions to food are the primary risk management steps taken to avoid serious health consequences. Mandatory regulation provides for more reliable and comprehensive coverage of the food supply than is afforded by voluntary measures and thereby, more certainty for consumers. Given the potential severity of risk associated with consuming allergens for allergic consumers, a mandatory approach is considered to be risk-proportionate.

2.3.1.1 Requirements for declaration of lupin as a food allergen

As described in section 1.2.3 above, existing ingredient labelling requirements apply to the use of lupin or lupin-derived ingredients in food. While many existing uses of lupin ingredients are declared in a statement of ingredients on food labels, some current and future applications may not be captured by these labelling requirements. For example, processing aids derived from lupin would not be required to be declared in a statement of ingredients; and foods that are not required to bear a label are not required to provide a statement of ingredients. This means that the presence of lupin ingredients in food may not always be declared to consumers.

In order to enable consumers to identify foods containing lupin and lupin-derived ingredients at all times, FSANZ has approved a variation to include lupin as a food allergen requiring mandatory declaration in Standard 1.2.3. Under the variation lupin, or products of lupin, must be declared when present as an ingredient, an ingredient of a compound ingredient, or as a food additive or processing aid (including when used as an ingredient or component of these). Where a food is not required to bear a label (e.g. when the food is unpackaged or is made and packaged on the premises), the declaration must be displayed in connection with the display of the food, or provided to the purchaser on request.

With respect to oils, although FSANZ understands there is currently no market presence of lupin oils in Australia or New Zealand, were there to be such, the draft variation (Schedule 10) requires oil sourced from lupin to declare the specific source name e.g. "lupin".

2.3.2 Inadvertent presence and voluntary initiatives

FSANZ recognises there is a residual risk to lupin-allergic consumers due to inadvertent presence.

Food laws place the onus on manufacturers to ensure their food is safe and suitable. Managing risks from possible cross-contamination of allergens can be aided by the use of voluntary tools developed and managed by the food industry. For example, the Voluntary Incidental Trace Allergen Labelling program (known as [VITAL](http://allergenbureau.net/vital/)¹¹) developed by the Allergen Bureau for use in Australia and New Zealand is a standardised allergen risk management process for the food industry that advises where a precautionary statement (e.g. 'may be present') should be included (or not) on the label to inform consumers about the possible presence of allergens due to unintentional cross-contact. The Australian Food and Grocery Council (AFGC) has also developed the [Food Industry Guide to Allergen Management and Labelling](#)¹² which provides an overview of the requirements outlined in the Code regarding food allergens that require labelling, guidance on the control and management of allergens in the manufacture of foods, and guidelines for declaring mandatory and voluntary allergen information for foods.

¹¹ <http://allergenbureau.net/vital/> Accessed 30 January 2017

¹² Accessed 30 January 2017

2.3.3 Analysis of lupin in food

FSANZ sought advice on the analysis of lupin in food from analytical laboratories and Enzyme-Linked Immunosorbent Assay (ELISA) kit supply companies.

The information received confirmed that there are commercial ELISA test kits available to analyse lupin in food and such testing has been done (though in relatively limited numbers) in Australia.

It was indicated that some ELISA kits do not have comparable reactivity to all types of lupin species. It is important that the ELISA kits are tested against food containing Australian grown lupin (*L. angustifolius*) and the lupin predominately used in Europe (*L. albus*, white lupin and *L. luteus*, yellow lupin).

One analytical company indicated that their ELISA test kit does have known cross-reactivity problems with native soybean protein but not processed soy. All ELISA kits should be tested for cross reactivity to potential problematic proteins such as soy, chickpea and peanut.

There are other analytical tests available which include Polymerase Chain Reaction (PCR) and Lateral Flow Devices (LFD). PCR is an indirect analytical method since it detects DNA and not protein (the allergenic component). It has been indicated that PCR testing would not be advocated in samples where the DNA has been damaged by processing. LFD, like ELISA, use antibody-based detection of lupin protein so has similar limitations to ELISA methodology.

As for any analytical method an analytical laboratory should validate the kit with the food matrix being analysed. The onus remains on analytical laboratories to validate the kits with the food matrix being analysed, which FSANZ understands is standard industry practice.

2.4 Cost benefit analysis

A comprehensive Decision Regulation Impact Statement (RIS) has been completed and considered by the Office of Best Practice Regulation. The Decision RIS considered three options: status quo, voluntary measures, and regulation.

FSANZ considered that overall Option 3, a regulatory approach (a variation to include lupin and lupin products in section 1.2.3—4 so that mandatory allergen declaration requirements apply), was likely to have the greatest net benefit and was therefore the preferred option.

FSANZ considered that maintaining the status quo or a non-regulatory approach were not appropriate options for the following reasons:

- A regulatory option is appropriate for the high degree of risk posed by allergenic foods - lupin presents potentially serious health and safety consequences for a significant proportion of the food-sensitive community
- A regulatory option provides for:
 - A higher degree of compliance by industry
 - More comprehensive coverage of foods requiring declaration
 - Greater assurance for consumers that all relevant food products are captured
 - Reduced search and avoidance costs for consumers
 - Reduced health care costs.

The current legislative approach to allergen regulation has been supported and accepted by government and industry. Whilst there will be upfront costs implementing an allergen management system within a food business that does not presently have allergens in its products, managing an additional allergen within an existing allergen management system would impose a relatively small additional marginal cost. Implementation costs for Option 3 would not be any higher than the costs involved with implementation of an industry code of practice for responsible businesses. This option would reduce confusion, search and avoidance costs, and provide more certainty for food sensitive consumers and improve their wellbeing. Option 3 is risk-proportionate and a relatively low cost approach to manage a new food allergen.

The Decision RIS is at Attachment D.

2.5 Decision

Under the approved variation lupin is included in Standard 1.2.3 as a food allergen requiring declaration, and is included in Schedule 10 as requiring the specific source name to be declared where the source of oil is lupin.

The draft variation as proposed following assessment was approved with three amendments, which were to correct minor typographical errors in the drafting. The variation takes effect on the date of gazettal and is at Attachment A. Transitional arrangements are addressed below in section 3.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2.6 Risk communication

2.6.1 Consultation

Consultation is a key part of FSANZ's standards development process.

In September 2013, a targeted consultation was conducted seeking data and/or information on the likely costs (and any possible benefits) if lupin was regulated as a food allergen with subsequent mandatory declaration requirements consistent with current allergens. Businesses identified for this consultation were approached via email.

FSANZ also linked into a survey that the AFGC conducted on their product information forms (PIFs). The AFGC PIF survey included some questions about lupin and FSANZ followed up with companies who provided relevant responses. FSANZ received 10 responses.

In December 2014, FSANZ staff visited an ingredient manufacturer in NSW and four primary producers of lupin and lupin-derived products in WA to gain information on the supply chain and current practices.

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions were called in July 2016 to obtain the views of interested parties on a draft variation to the Code, and allowed for a six-week public consultation period. The call for submissions was notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified via email about the availability of reports from public comment.

In particular, FSANZ sought further information and feedback from the lupin industry and allergy susceptible individuals or organisations/groups representing such individuals on the proposed regulatory measure for potential impacts and costs, and for managing the allergen risks associated with lupin in food. Fourteen submissions were received, however as minimal quantitative information was obtained FSANZ conducted further targeted consultation in order to enhance the qualitative analysis where possible. This information was used to develop the Decision RIS at Attachment D. This analysis further supported the view of FSANZ that Option 3 provides the preferred option.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. All public comments received were reviewed and considered before approval of the variation to the Code by the FSANZ Board. All comments are valued and contributed to the rigour of the assessment.

FSANZ also acknowledges the expertise of members of the Food Allergy and Intolerance Advisory Group who advised on the risk assessment.

2.6.2 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.

FSANZ made notifications to the WTO in accordance with the WTO Agreement on Technical Barriers to Trade. Comment was received from the United States on a typographical error in the Call for Submissions which has been corrected (refer section 2.1 Table 1 above).

2.7 FSANZ Act assessment requirements

2.7.1 Section 59

2.7.1.1 Cost benefit analysis

A cost benefit analysis has been conducted (refer section 2.4) and FSANZ is of the view that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

Further detail is provided in the Decision RIS at Attachment D.

2.7.1.2 Other measures

Voluntary measures, such as a code of practice, were considered in the call for submissions however were not a preferred option due to the severity of risk posed by allergenic foods. FSANZ considers there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

2.7.1.3 Any relevant New Zealand standards

The affected standards apply in both New Zealand and Australia.

2.7.1.4 Any other relevant matters

Although FSANZ is not aware of any confirmed cases of lupin allergy in New Zealand and it is currently not used in New Zealand to any significant extent as a food ingredient, the draft variation will apply in New Zealand. As lupin food products become more popular in Australia, it is likely that the products will also increase in popularity in New Zealand. This in turn will lead to greater risk of susceptible individuals developing lupin allergy.

In addition, applying the draft variation to both Australia and New Zealand maintains trans-Tasman consistency in food allergen regulation.

Other relevant matters are considered below.

2.7.2. Subsection 18(1)

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

2.7.2.1 Protection of public health and safety

Protection of public health and safety is FSANZ's most important objective in standards development. In regard to the use of lupin and lupin-derived products as ingredients in food, FSANZ has concluded that the mandatory declaration requirements according to section 1.2.3—4 and the requirement to specify the source name of lupin oil in Schedule 10, will support the primary objective of protecting public health and safety. These measures are expected to lower the risk of future lupin allergen-based reactions (including possible cross-reactions in people allergic to other food allergens, such as peanuts or soy), in Australia and New Zealand.

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

The mandatory declaration requirements will ensure that consumers have access to information about the presence of lupin as an ingredient, an ingredient of a compound ingredient, or a food additive or processing aid (or an ingredient or component of these), in both labelled and unlabelled foods. People who are allergic to lupin will therefore be able to identify more reliably the presence of lupin and lupin-derived ingredients in a food and could make a choice to avoid the food product. In addition, for those people who are allergic to other legumes, e.g. peanut and soy, and are aware of the potential for cross-reactivity with lupin, the declaration of lupin will help them to make informed choices.

2.7.2.3 The prevention of misleading or deceptive conduct

The requirement to declare the presence of lupin and lupin-derived ingredients in food does not raise any issues in relation to this objective.

2.7.3 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 of allergy from consumption of lupin in food, (see SD1). The risk assessment was based on the best scientific evidence available to FSANZ.

It considered all available information (national and international), including prevalence and cross-reactivity with other known food allergens.

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

The proposed variation to require mandatory declaration of the presence of lupin and lupin-derived ingredients in food is consistent with EU legislation. Many other regions have legislation addressing labelling for allergens however the particular allergens requiring declaration vary between regions depending on the local public health significance. Mandatory labelling of lupin as a food allergen is not currently required in other jurisdictions other than Europe. The lack of requirement for labelling in a particular country is likely to be due to a variety of reasons, which may include, the prevalence of food containing lupin in the country, the genetic disposition of the population and the country's approach to food risk.

The requirement for mandatory allergen declaration for lupin in the Code in Australia and New Zealand will be consistent with food standards in Europe, but different to other countries such as Canada and the USA. However FSANZ considers taking the proposed approach to this issue is justified on the grounds of public health and safety, particularly considering that in specific parts of Australia e.g. WA, there is an industry focused on lupin production for human food use.

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

Requiring the declaration of lupin in Australia and New Zealand will create a 'level playing field' between these two countries and Europe. The mandatory declaration requirement for lupin will mean that there is an inconsistency with other Australia and New Zealand trading partners and that there would be an additional burden on them if they import lupin containing food into Australia or New Zealand. However, the requirement will strengthen the reputation of Australia and New Zealand for safe food and responsible approaches to labelling. It is expected that the major source of lupin containing foods, external to Australia, would be from the highly developed production of lupin in Europe, rather than other parts of the world. Thereby, the potential impact on non-European trading partners exporting into Australia or New Zealand is expected to be small, if at all.

- **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 Forum on Food Regulation**

There are no relevant policy guidelines for this Proposal.

3 Transitional arrangements

The draft variations to sections 1.2.3—4 and S10—2, will commence on the date of gazettal and will have a 12-month transitional period from commencement of the variation. On expiration of the transitional period, all products affected by this variation, including stock-in-trade items, must comply with the variation.

FSANZ considers a 12-month transitional period is an appropriate time period which balances the risk of a serious health outcome versus the resources needed by industry to comply with the requirement and taking account of labelling costs.

The current use of lupin in food in Australia and New Zealand is minor, with most products already indicating the presence of lupin (either as a consequence of current ingredient labelling requirements in the Code or voluntary labelling).

4 References

Björkstén B, Crevel R, Hischenhuber C, Løvik M, Samuels F, Strobel S, Taylor SL, Wall JM, Ward R (2008) Criteria for identifying allergenic foods of public health importance. *Regul Toxicol Pharmacol* 51: 42-52.

van Bilsen JH, Romans S, Crevel RW, Rona RJ, Przyrembel H, Penninks AH, Contor L, Houben GF (2011) Evaluation of scientific criteria for identifying allergenic foods of public health importance. *Regul Toxicol Pharmacol* 60: 281-289.

WHO (2000) Technical Report Series-896. Report of an ad hoc panel on food allergens. 53rd Report of JECFA, Annex 4:124-128.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)
- D. Decision Regulation Impact Statement (OBPR ID: 20235)

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



Food Standards (Proposal P1026 – Lupin as an Allergen) 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 P1026 – Lupin as an Allergen) Variation.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Standard 1.2.3** is varied by

[1.1] inserting after section 1.2.3—1

1.2.3—1A Transitional arrangements for prescribed variations

(1) For the purposes of this section:

prescribed variation means the amendment made by the Variation to paragraph 1.2.3—4(1)(b).

transitional period means the period commencing on the Variation's date of commencement and ending 12 months after the commencement.

the Variation means the *Food Standards (Proposal P1026 – Lupin as an Allergen) Variation*.

(2) Section 1.1.1—9 of Standard 1.1.1 does not apply to the prescribed variation.

(3) During the transitional period, a food product may comply with either:

- (a) the Code as in force without the prescribed variation; or
- (b) the Code as amended by the prescribed variation;

but not a combination of both.

[1.2] omitting from paragraph 1.2.3—4(1)(b)

- (ix) tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*.

substituting

- (ix) tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*;
- (x) lupin.

[2] **Schedule 10** is varied by

[2.1] omitting “1.2.4—4(b)(i)” from Note 1, substituting “1.2.4—4(b)(iii)”

[2.2] inserting after section S10—1

S10—1A Transitional arrangements for prescribed variations

(1) For the purposes of this section:

prescribed variation means the amendment made by the Variation to paragraph (a) under the entry for “fats or oils” in the table to section S10—2.

transitional period means the period commencing on the Variation's date of commencement and ending 12 months after the commencement.

the Variation means the *Food Standards (Proposal P1026 – Lupin as an Allergen) Variation*.

(2) Section 1.1.1—9 of Standard 1.1.1 does not apply to the prescribed variation.

(3) During the transitional period, a food product may comply with either:

- (a) the Code as in force without the prescribed variation; or
- (b) the Code as amended by the prescribed variation;

but not a combination of both.

[2.3] omitting from paragraph (a) under the entry for “fats or oils” in the table to section S10—2

(ii) if the source of oil is peanut or sesame—the specific source name; and

substituting

(ii) if the source of oil is lupin, peanut or sesame—the specific source name; and

Attachment B – 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 P1026 to consider risk management options to mitigate the risk of allergic reactions in sensitive individuals to food containing lupin or lupin products. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation to Standard 1.2.3 and Schedule 10.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, 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 *Legislation Act 2003*.

2. Purpose

The Authority has prepared a draft variation to amend Standard 1.2.3 and Schedule 10 to require declarations relating to the presence of lupin and/or lupin products in food; and declarations of the source name of any oil where the source of that oil is lupin. The purpose of the amendments is to mitigate the risk of allergic reactions in sensitive individuals to food containing lupin or lupin products due to the risk to public health and safety of unidentified lupin in food.

The draft variation also deals with an editorial correction to Note 1 to Schedule 10.

3. Documents incorporated by reference

The variations does 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 P1026 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

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

Item 1 amends Standard 1.2.3.

Subitem [1.1] inserts section 1.2.3—1A into Standard 1.2.3 to provide transitional arrangements in relation to the amendment made to paragraph 1.2.3—4(1)(b). The effect of section 1.2.3—1A is that the usual stock-in-trade provision in section 1.1.1—9 of Standard 1.1.1 will not apply to that amendment. Instead, there will be a 12-month transitional period commencing on the Variation's date of commencement. During that transitional period, a food company will be able to comply with either:

- the Code as in force without the amendment to paragraph 1.2.3—4(1)(b); or
- the Code with the amendment to paragraph 1.2.3—4(1)(b),

but not a combination of both. When the transitional period expires, all products affected by the amendment to paragraph 1.2.3—4(1)(b), including stock-in-trade items, must comply with that amendment.

Subitem [1.2] inserts a new subparagraph into paragraph 1.2.3—4(1)(b) to include lupin in the list of foods or products of the foods, which if present in a food for sale, must have their presence declared.

The effect of this amendment is that any food for sale, which contains lupin or lupin products as an ingredient; an ingredient of a compound ingredient; a food additive or processing aid (or an ingredient or component of these), must have a declaration of the presence of lupin or lupin products on the label on a package of the food. Where the food is not required to bear a label (for example, when the food is unpackaged or is made and packed on the premises), the declaration of the presence of lupin or lupin products must be provided in labelling that either accompanies the food or is displayed in connection with the food; or provided to the purchaser on request.

The declaration will be required regardless of the amount of lupin or lupin products present in the food for sale.

Item 2 amends Schedule 10.

Subitem [2.1] corrects an editorial error in Note 1 of Schedule 10 by replacing the reference to "1.2.4—4(b)(i)" with a reference to "1.2.4—4(b)(iii)". This amendment commences on the date of gazettal of the variation.

Subitem [2.2] inserts section S10—1A into Schedule 10 to provide transitional arrangements in relation to the amendment to section S10—2. The effect of section S10—1A is that the usual stock-in-trade provision in section 1.1.1—9 of Standard 1.1.1 will not apply to that amendment. Instead, there will be a 12 month transitional period commencing on the Variation's date of commencement. During that transitional period, a food company will be able to comply with either:

- the Code as in force without the amendment to section S10—2; or
- the Code with the amendment to section S10—2,

but not a combination of both. When the transitional period expires, all products affected by the amendment to section S10—2, including stock-in-trade items, must comply with that amendment.

Subitem [2.3] amends the table to section S10—2 by including lupin in subparagraph (ii) in paragraph (a) under the entry for “fats or oils” in that table. The effect of this amendment is that, if the source of an oil is lupin, the statement of ingredients (as required by Standard 1.2.4) must declare lupin as the source name of the oil.

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



Food Standards (Proposal P1026 – Lupin as an Allergen) 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 P1026 – Lupin as an Allergen) Variation.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Standard 1.2.3** is varied by

[1.1] inserting after section 1.2.3—1

1.2.3—1A Transitional arrangements for prescribed variations

(1) For the purposes of this clause:

prescribed variation means the amendment made by the Variation to paragraph 1.2.3—4(1)(b).

transitional period means the period commencing on the Variation's date of commencement and ending 12 months after the commencement.

the Variation means the *Food Standards (Proposal P1026 – Lupin as an Allergen) Variation*.

(2) Section 1.1.1—9 of Standard 1.1.1 does not apply to the prescribed variation.

(3) During the transition period, a food product may comply with either:

- (a) the Code as in force without the prescribed variation; or
- (b) the Code as amended by the prescribed variation;

but not a combination of both.

[1.2] omitting from paragraph 1.2.3—4(1)(b)

- (ix) tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*."

substituting

- (ix) tree nuts, other than coconut from the fruit of the palm *Cocos nucifera*;
- (x) lupin.

[2] **Schedule 10** is varied by

[2.1] omitting "1.2.4—4(b)(i)" from Note 1, substituting "1.2.4—4(b)(iii)"

[2.2] inserting after section S10—1

S10—1A Transitional arrangements for prescribed variations

(1) For the purposes of this section –

prescribed variation means the amendment made by the Variation to paragraph (a) under the entry for "fats or oils" in the table to section S10—2.

transitional period means the period commencing on the Variation's date of commencement and ending 12 months after the commencement.

the Variation means the *Food Standards (Proposal P1026 – Lupin as an Allergen) Variation*.

(2) Section 1.1.1—9 of Standard 1.1.1 does not apply to the prescribed variation.

(3) During the transition period, a food product may comply with either –

- (a) the Code as in force without the prescribed variation; or
 - (b) the Code as amended by the prescribed variation;
- but not a combination of both.

[2.3] omitting from paragraph (a) under the entry for “fats or oils” in the table to section S10—2

“(ii) if the source of oil is peanut or sesame—the specific source name;
and”

substituting

“(ii) if the source of oil is lupin, peanut or sesame—the specific source
name; and”

Attachment D – COAG Decision Regulation Impact Statement (OBPR ID: 20235)



Lupin as an Allergen

Executive summary

This Decision Regulation Impact Statement (DRIS) has been prepared for Proposal 1026 – Lupin as an allergen. The DRIS provides an examination of the options available for managing potential health and safety outcomes of allergic reactions to lupin in the Australia and New Zealand populations from a costs and benefits point of view.

An allergic reaction is the clinical manifestation which occurs in some individuals when the immune system responds to a protein (allergen), as if it were a threat. For some allergic individuals the presence of the protein will only result in tingling and itchy feeling in the mouth and hives anywhere on the body but for others will cause swelling in the face, throat or mouth, difficult breathing and abdominal pain, nausea and vomiting. Anaphylaxis, the most severe allergic reaction, which includes swelling of the air-ways and resulting difficulty in breathing, occurs rapidly and can be fatal. The severity of any reaction can vary between individuals but also for individuals at different times. Australia and New Zealand were among the first countries to recognise the need to regulate food allergens with the introduction, in 2002, of mandatory declaration requirements in the *Australia New Zealand Food Standards Code* (the Code).

Lupin belongs to the group of plants known as legumes and contains proteins which are similar to those found in other allergenic legumes such as peanut and soy. Hence proteins present in lupin may also be an allergen for some members of the community. The risk assessment undertaken by FSANZ, using internationally accepted criteria (WHO, 2002), concluded that lupin is an emerging food allergen of public health significance in Australia and New Zealand. As more products containing lupin become available (from Australia or from other geographical regions, such as Europe) the number of individuals in Australia and New Zealand experiencing allergic reactions to lupin is likely to increase.

The true prevalence of various food allergies in the population is uncertain. However, prevalence estimates reported in the medical literature for peanut allergy range between 0.7 to 1.4% of the population in Australia and New Zealand. In view of the known immunological cross-reactivity between peanut and lupin antigens the number of people 'at risk' may be estimated from the prevalence of peanut allergies in Australia and New Zealand. If we assume 1.1% (an average of the reported range estimates) of the population then that would equate to around 250,000 individuals in Australia and around 50,000 in New Zealand. This estimate does not take into account situations in which lupin-specific proteins are the main allergens i.e. their immune system may not cross-react to peanut-associated protein or where allergy to lupin is associated with cross-reactivity with other legumes such as soy.

Lupin is currently not included as an allergen in the Code and its presence in food may not always be declared. Mandatory labelling of lupin as an allergen has been in place in Europe since 2007. Major food allergens currently listed in the Code for Australia and New Zealand include wheat, crustacea, egg, fish, milk, peanuts, sesame seeds, soybeans, tree nuts.

These foods and their products must be declared whenever they are present in a food as an ingredient, ingredient of a compound ingredient, food additive or processing aid (or ingredient or component of these). This declaration is required either on the label of the food, or where a label is not required (e.g. unpackaged food or in restaurants), displayed in connection with the food or provided on request, so that at risk consumers can avoid consuming allergens present in food.

A Consultation RIS (OBPR Reference 20235), consistent with the Council of Australian Government's (COAG) best practice regulation requirements, was released for consultation from 16 June 2016 to 28 July 2016 with a Call for Submissions. Three options were presented:

- Option 1: Maintain the status quo
- Option 2: Prepare an industry Code of Practice for food manufacturing industries that would recommend voluntary allergen declarations for lupin
- Option 3: Prepare a draft variation to include lupin and lupin products in section 1.2.3—4 so that mandatory allergen declaration requirements apply

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

FSANZ considers that overall Option 3, a regulatory approach (prepare a draft variation to include lupin and lupin products in section 1.2.3—4 so that mandatory allergen declaration requirements apply), is likely to have the greatest net benefit and is therefore the preferred option.

FSANZ considers that maintaining the status quo or a non-regulatory approach are not appropriate options for the following reasons:

- A regulatory option is commensurate with the high degree of risk posed by allergenic foods - lupin presents potentially serious health and safety consequences for a significant proportion of the food-sensitive community
- As such, a regulatory option provides for:
 - A higher degree of compliance by industry
 - More comprehensive coverage of foods requiring declaration
 - Greater surety for consumers that all relevant food products are captured
 - Reduced wellbeing (search and avoidance) costs for consumers
 - Reduced health care costs.

The current food allergen management framework has been supported and accepted by government and industry. Adding an additional allergen to an existing allergen management framework would only impose a marginal cost of updating an existing framework for businesses. Implementation costs for Option 3 would not be any higher than the costs involved with implementation of an industry code of practice for responsible businesses. This option would reduce confusion, search and avoidance costs, and provide more certainty for food sensitive consumers and improve their wellbeing. Option 3 is risk-proportionate and a relatively low cost way to manage a new food allergen.

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1 Introduction

Proposal P1026 was prepared to assess the public health and safety outcomes of allergic reactions to lupin in the Australia and New Zealand populations and to develop appropriate risk management strategies to manage these outcomes, including consideration of a need for food regulatory measures in the *Australia New Zealand Food Standards Code* (the Code)¹³.

This Decision Regulation Impact Statement (DRIS) has been prepared to provide an examination of the cost and the benefits of various options for managing potential health and safety outcomes of allergic reactions to lupin in Australia and New Zealand.

Lupin is an emerging food allergen of public health significance in Australia. However, its presence in food may not always be declared. Major food allergens listed in the Code include wheat, crustacea, egg, fish, milk, peanuts, sesame seeds, soybeans, tree nuts. The products of these foods must be declared whenever they are present in a food as an ingredient, ingredient of a compound ingredient, food additive or processing aid (or ingredient or component of these). This declaration is required either on the label of the food, or where a label is not required (e.g. unpackaged food) information must be displayed in connection with the food or provided on request so that at risk consumers can avoid consuming allergens present in food.

FSANZ has made considerable effort to engage with and understand the lupin 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.

The DRIS 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 summary of submissions and FSANZ's responses from the Approval Report is provided in Attachment 1.

1.1 Food allergy

Allergies are an important health issue due to the potential for severe and life threatening reactions. An allergy is the clinical manifestation e.g. itching, shortness of breath, swelling of the face, which occurs when the immune system responds to a food specific protein (allergen), as if it were a threat.

An ASCIA-Access Economics Report¹⁴ estimates the financial cost of allergies in Australia to be around \$9.7 billion per annum.¹⁵

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

¹⁴ ASCIA-Access Economics Report (2007)

http://www.allergy.org.au/images/stories/pospapers/2007_economic_impact_allergies_report_13nov.pdf please note these cost have been indexed to 2016 using [ABS Cat. No. 6401.0, Consumer Price Index](#).

¹⁵We could not find any reports on the economic or financial cost of allergies in New Zealand

To put this financial cost in perspective, it is more than twice as large as schizophrenia (\$2.2 billion) and bipolar affective disorder (\$2 billion) combined. Additionally, the net value of the lost wellbeing (disability and premature death) was a further \$27 billion or 156,144 Disability Adjusted Life Years (DALYs). This represents almost double the same figures for either arthritis or hearing loss (both \$14.5 billion).

Australia and New Zealand were among the first countries to recognise the need to regulate food allergens with the introduction, in 2002, of mandatory declaration requirements in the *Australia New Zealand Food Standards Code* (the Code).

Well-known food allergens include wheat, crustacea, egg, fish, milk, peanuts, sesame seeds, soybeans and tree nuts. As our choice of food options expands due to new foods and ingredients entering the food supply, the likelihood that consumers will encounter new food allergens also increases.

FSANZ research¹⁶ suggests that in the first five years from the introduction of mandatory allergen declarations the proportion of severe reactions which were attributed by survey respondents to 'unlabelled/incorrectly labelled food' decreased from 14 per cent to 5 per cent.

Allergy experts estimate that the population with food allergy is likely to be 10–20 fold higher than the population who experience anaphylaxis¹⁷. Whilst valuable, information on the incidence of severe reactions represents just the 'tip of the iceberg', but underestimates the size of the population at risk. For allergic individuals and their carers, the threat of reaction is chronic and the timing of an acute reaction is unpredictable. In addition, the severity of the reaction is unpredictable; the same individual can experience a different severity of reaction on different occasions. The reason for this variation is multi-factorial and at times unknown. As a result of these unpredictable elements, the majority of food allergic patients and their carers live with being at risk, but without knowing exactly the nature or extent of the risk.

Currently there is no cure for food allergies. What causes food allergy to develop in some people is not yet fully understood, but a complex interaction between genetic and environmental factors is likely to be involved. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are the primary risk management steps taken to avoid serious health consequences.

According to information provided by allergy awareness groups such as the Australian Society for Clinical Immunology and Allergy, Allergy New Zealand and Allergy and Anaphylaxis Australia on prevention of food allergy in general, avoidance of the food allergen is the key preventative strategy. Similarly EFSA (2014) conclude that dietary avoidance is a mainstay for management of food allergy. Declaring allergens on packaged food labels and requiring this information to be available for foods not bearing a label is seen as a critical risk management tool in the avoidance of food allergy in susceptible consumers.

1.1.1 Economic impact of food allergy

Once diagnosed, the only treatment currently available for most individuals is prevention. Individuals need to adopt avoidance strategies, which usually consists of complete dietary exclusion of the problem food. Such strategies are only effective if complete, accurate and understandable labelling of food is available.

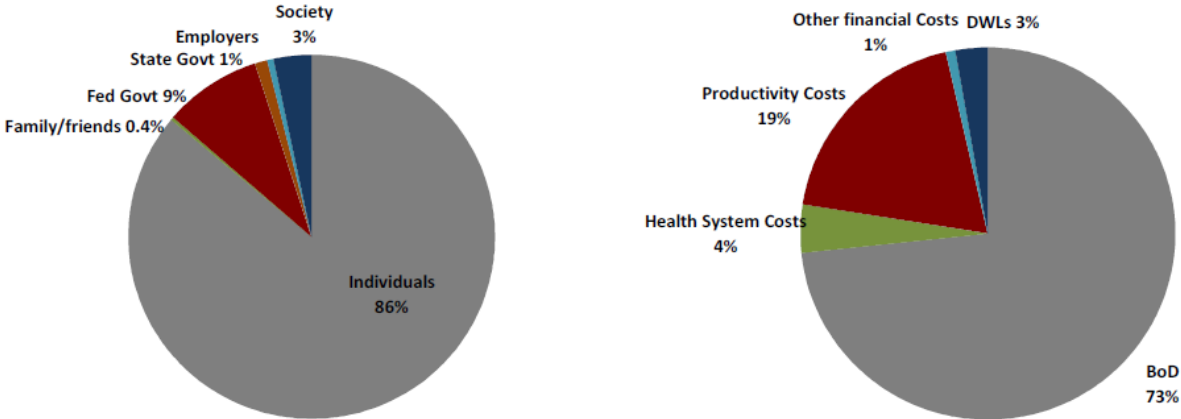
¹⁶ [Supporting document 3](#) - Rapid evidence assessment on consumer understanding, attitudes and behaviour with respect to food allergen labelling

¹⁷ Kemp, AS and Wu W (2008) Food allergy and anaphylaxis – dealing with uncertainty. *Medical Journal of Australia*, 188 (9):503-504

Emergency treatment strategies are available for those at risk of severe reactions, ranging from self-administered adrenalin and follow-up medical supervision, to admission to hospital. Allergy sufferers need to learn to identify and avoid products containing the problem foods, and what to do if any is accidentally ingested or if they experience symptoms of reaction.

Consequently, the economic impact of food allergy may be widespread and affect many sectors of society. A large population of individuals is likely to be affected, with associated costs to themselves, their carers and their households, potentially over a lifetime. In the health sector, resources required for food allergy diagnosis, support and education compete with other pressures on limited health care resources especially in publicly funded health systems.

ASCIA-Access Economics Report¹⁴, estimates financial cost¹⁸ of around \$2,369 per person with allergies per annum. Including the value of lost wellbeing, the economic cost¹⁹ is \$8,920 per person per annum. Individuals with allergies bear 48% of the financial costs, and their families and friends bear a further 1%. Federal government bears 32% of the financial costs; State and Territory governments bear around 5% of the costs, with the remaining 13% borne by others in society (including employers). If the burden of disease (the economic cost of disability and premature death)²⁰ is included, individuals bear 86% of the costs. Total cost shares are depicted in the following charts.



Picture 1: Total cost of allergies, by type of cost and by bearer (% total)¹⁴

A diagnosis of food allergy has a significant effect on quality of life in children and their parents, comparable on formal measurement with having a child with insulin dependent diabetes. The source of stress is related more to perceptions of risk than actual episodes of allergic reactions, and the need for planning for outings, school camps, preparation of special meals and the need to liaise with other caregivers such as school and preschool staff.

1.1.1 Lupin as a Food Allergen

Lupin is a legume and is related to other legumes such as peanut and soy, which have proteins which are allergenic for some consumers. In Australia and New Zealand lupin allergy is currently not as well-known or as prevalent as peanut or soy allergies.

¹⁸ Total financial costs comprise both direct medical costs and the indirect costs of lost productivity and the deadweight costs of additional taxation.
¹⁹ Total economic costs comprise total financial costs plus the human welfare costs of pain and suffering caused by allergies and raised risk of premature death.
²⁰ The disability, loss of wellbeing and premature death that result from allergic disease are more difficult to measure, but have been analysed in this chapter in terms of the years of healthy life lost, both quantitatively and qualitatively, known as the 'burden of disease', with an imputed value of a statistical life year (VSLY) so as to compare these costs with financial costs of allergy.

The prevalence is lower than for the other common allergens, at least partly, due to the current lower use of lupin-derived ingredients compared with peanut or soy. In Europe, where lupin is more widely used in food products there has been mandatory allergen labelling for food products containing lupin since 2007.

Lupin allergy symptoms range from mild to severe, consistent with other food allergens. Mild symptoms include tingling and itchy feeling in the mouth, and hives anywhere on the body. More serious symptoms include swelling in the face, throat or mouth, difficulty in breathing and abdominal pain, nausea and vomiting. The severity of allergic reactions varies from person to person and even in the same person at different times. Anaphylaxis, the most severe allergic reaction, which includes swelling of the air-ways and resulting difficulty in breathing, occurs rapidly and can be fatal. Allergic reactions, including anaphylactic episodes are unpredictable and can only be diagnosed retrospectively. The aetiology of the variability in the severity of allergic reactions in the same individual is not known, although it may in part be associated with level of intake. Due to the nature of allergy, any allergic individual is at risk of experiencing an anaphylactic reaction. Foods are the most common triggers of anaphylaxis in infants and young children.

Sensitisation is the initial step in the allergic process, regarded as a “risk marker” for developing allergy symptoms; it may or may not lead to clinical manifestation i.e. allergy. However there is no way to predict if/when a sensitised individual will become allergic. Similarly there is no way of predicting the severity of an allergic reaction. As a sensitised individual may convert to be an allergic one at any time it is important to consider data on sensitised individuals as well as allergic ones. Where an individual is known to have sensitivity to lupins or a potential cross-reactivity health professional advice would most likely be to undertake further investigations and/or avoid consuming lupins.

Food allergy can occur either as a result of cross-reactivity with other allergens or as a primary reaction to the particular food. In the case of primary reaction, the person’s immune system recognises proteins in a food as “foreign” and reacts to them as a threat. For the cross-reactivity situation, an individual is initially allergic to a particular food (e.g. peanuts) and because of similarities between the proteins in another food (e.g. lupin), they develop sensitivity to that other food as well (in this case lupin). It should be noted not all people with allergy/sensitivity to the first food will become allergic/sensitive to the second food.

Skin prick tests (SPTs) and allergen-specific antibody (IgE) tests are used as risk indicators of an allergic response, in that they identify sensitisation, but cannot be used in isolation to diagnose allergy to a particular food (EFSA, 2014). Food allergy is diagnosed using a variety of tools, most importantly family and clinical history, food diaries, food elimination diets and food challenges.

As a sensitised individual can convert to being allergic it is important to consider, as part of this assessment, the prevalence of lupin sensitisation. The route of sensitisation in Australia is unknown, and may be due to ingestion, environmental exposure to lupin pollen and lupin flour dust, or transcutaneous absorption. However, it is clear that the current level of exposure to lupin in Australia can lead to sensitisation and clinically relevant allergy to lupin-containing food products.

From the clinical investigation of lupin allergy in Australia²¹ it has been concluded that among the common food allergens, sensitisation and clinical allergy to lupin in children appears to be most comparable in frequency and severity to soy.

²¹ Loblay et al, 2009-unpublished data

Although lupin allergy is commonly seen in association with peanut allergy, it is equally common in children sensitised to tree nuts and to egg, and may also occur as an isolated phenomenon without peanut sensitisation. Severe reactions have been documented, particularly in adults sensitised to lupin alone.

In October 2006, the then Australia and New Zealand Food Regulation Ministerial Council (now known as the Australia and New Zealand Ministerial Forum on Food Regulation) requested FSANZ to review the regulatory management of food allergens. In December 2010 FSANZ released the report of this review (FSANZ Review of Regulatory Management of Food Allergens)²². One of the recommendations of the report was to develop a proposal to assess whether lupin and lupin-derived products should be included in the list of allergens requiring mandatory declaration in Standard 1.2.3 (Information requirements - warning statements, advisory statements and declarations) of the Code. This Decision RIS is part of that Proposal.

1.2 Use of lupin and lupin production

Lupin is a member of the legume family like peanut, soy, pea, bean and lentil. There are over 450 species within the *Lupinus* genus. Some of these, commonly known as sweet lupin, are used for human and animal food. Historically most of the Australian sweet lupin (*Lupinus angustifolius*) crop was used for animal feed or exported to overseas markets. Lupin is now being recognised as a valuable addition to the human food supply due to its high protein and fibre content, and being gluten-free. As a result of the increased interest in using lupin-derived products in food available in Australia, it is expected that in addition to the Australian sweet lupin, other varieties of lupin will also be cultivated in Australia or imported to satisfy demand. White lupin (*Lupinus albus*) and yellow lupin (*Lupinus luteus*) are two other cultivated species widely used in food production in Europe.

In the last few years, use of lupin-derived ingredients (such as flour, grits and bran) have increased in food products produced in Australia, and the lupin industry sees strong potential in the development of uses of various lupin products in food. Lupin flour and bran are used in a variety of products e.g. baked goods such as bread, biscuits, muffins and cakes, pasta products and sauces. Also, there are few imported lupin products available in Australia and New Zealand. From information received, lupin food products for human consumption are not widely available in New Zealand currently, nor is there a lupin primary industry in New Zealand directed at human food production. This however may change over time as lupin products become more popular in Australia and information on potential health benefits spreads.

Western Australia (WA) accounts for the majority of Australian lupin production and exports.²³ The current gross value of lupin production in WA is \$150 million. Lupin is grown in the WA wheat belt as a rotational crop, having an important role in breaking cereal disease cycles and to fix nitrogen in the soil for the next wheat crop. About 40% of lupin production in WA is retained on-farm as stock feed and seed or is traded on the domestic market to supply the sheep, dairy, pigs and poultry industries. WA also produces the majority of lupin sold into the international market for animal feed.

The vast majority of global lupin production is used for animal feed (ruminants such as sheep and cattle, and a growing use in aquaculture). Less than 4% of global production is currently consumed as human food. It has been estimated that about 500,000 tonnes of food containing lupin ingredients are consumed each year in Europe.

²² [Food Standards Australia New Zealand \(FSANZ\) - Review of the regulatory management \(2010\)](#)

²³ [Western Australian Department of Agriculture and Food, 2014](#)

These food products are mainly used where lupin flour has been added to wheat flour to produce baked goods. Use as a human food commodity is becoming more common in Australia due to current interest in the 'health foods' market including:

- the nutritional benefits of high protein, high fibre and low fat content
- it is gluten free; and
- it can be a more cost-effective alternative to ingredients such as soy.

Identified current uses of lupin as a human food in Australia are its use as an ingredient in foods, such as pasta, sauces, soups, bread, cakes and muffins. In New Zealand, based on FSANZ's knowledge, the current uses of lupin as a human food are (to date) more limited than in Australia (e.g. imported instant soup, instant Asian based meals, baked goods).

Other potential uses of lupin in food, which are being researched or are available outside Australasia, and may result in future food products in Australia and New Zealand containing lupin, include:

- a source of protein in body-building powders
- as a food additive e.g. as an alternative source of lecithin, as a bulking agent in processed meat products
- as a processing aid e.g. emulsifier in meats and the cold-cut industry
- as a lactose replacement in milk/lactose free ice-cream
- as a replacement for soy e.g. in miso sauce or tempura batter
- as a dairy milk substitute e.g. similar to soy, nut, seed and cereal milk alternatives.

1.3 The current regulatory arrangements

Food sold in Australia and New Zealand is required to declare the presence of certain foods or substances as listed in section 1.2.3—4 of the Code. The declaration must be provided on the label on a package of the food, or for foods that are not required to bear a label, shown in connection with the display of the food or provided to the purchaser on request (Standard 1.2.1 – Requirements to have labels or otherwise provide information). These requirements have been in place since December 2002 when the Code first came into effect.

Currently, the following substances or foods or product of these foods must be declared (with some exceptions):

- cereals containing gluten, namely, wheat, rye, barley, oats, spelt and their hybridised strains
- crustacea
- egg
- fish
- milk
- peanuts
- soybeans
- tree nuts
- sesame seeds
- added sulphites in concentrations of 10 mg/kg or more.

This declaration applies when the listed substances or foods are present as:

- an ingredient or as an ingredient of a compound ingredient; or
- a food additive or an ingredient or component of a food additive; or

- a processing aid or an ingredient or component of a processing aid.

In addition, Schedule 10 (Generic names of ingredients and conditions for their use) of the Code requires that oil derived from peanut, soybean (exceptions apply) or sesame declare the specific source name in the ingredient list, instead of using the generic term 'vegetable oil'.

Currently, the use of lupin as an ingredient in food is subject to the ingredient labelling requirements in Standard 1.2.4 (Information requirements – statement of ingredients) of the Code. This Standard requires most packaged foods to declare each ingredient in a statement of ingredients using the common name of the ingredient, or a name that describes the true nature of the ingredient, or a generic name (listed in Schedule 10 of the Code). However, small packages (defined as packages with a surface area less than 100 cm²), or foods that are not required to bear a label (e.g. when the food is unpackaged or is made and packaged on the premises such as in a bakery or restaurant), do not require a statement of ingredients making it difficult for consumers of such products who may be allergic to lupin to make informed purchasing decisions.

Furthermore, there are some potential uses of lupin in food products in Australia and New Zealand that could lead to instances where the presence of lupin ingredients does not currently need to be declared on the label of the food. For example:

- the use of lupin as a processing aid would not currently be required to be declared as processing aids are exempt from ingredient labelling (section 1.2.4—3)
- food additives that are derived from lupin, such as lecithin, would only be required to declare the food additive name or number (e.g. 'lecithin' or '322') but not the lupin source (section 1.2.4—7)
- the use of lupin as an ingredient of a compound ingredient would not be required to be declared if the compound ingredient makes up less than 5% of the final food and the lupin does not perform a technological purpose (section 1.2.4—5).

However, if lupin was listed in section 1.2.3—4, its presence would be required to be declared in each of the instances identified above allowing consumers who may be sensitive to identify lupin and make informed purchasing decisions.

1.4 Industry practices

The Australian Food and Grocery Council (AFGC) has prepared *The Food Industry Guide to Allergen Management and Labelling*²⁴ that provides guidance for industry in managing and labelling food allergens. This Guide is relevant to all sectors of the food industry involved in the supply, handling, production, distribution and sale of foods and encompasses members of the AFGC. It provides recommendations for the production and labelling of foods containing allergenic substances as listed in the Code.

This guide provides:

- an overview of the mandatory allergen labelling requirements outlined in the Code
- an overview of the incidence and symptoms of food allergy and food intolerances and the substances in food that may provoke allergic reactions
- guidance on the control and management of allergens in the manufacture of foods

²⁴ <http://www.afgc.org.au/download/655/>

- information on testing for allergens
- guidelines for declaring mandatory and voluntary allergen information for foods
- an outline of VITAL (Voluntary Incidental Trace Allergen Labelling)²⁵.

The guide recommends a consistent approach in the presentation of allergen information to help allergic consumers more quickly and easily identify foods of concern, helping to minimise accidental consumption of unsuitable foods.

The recommended format consists of:

- an ingredient list declaring in bold allergenic substances and their derivatives; and
- an allergen summary statement; and
- a precautionary statement (only if appropriate).

In regards to the precautionary statement (i.e. 'may be present'), the guide talks about this being made by food manufacturers and importers on a voluntary basis²⁶ and being appropriate when, despite all reasonable measures, the inadvertent presence of allergens in food is unavoidable. The guide recommends the precautionary statement be used in conjunction with VITAL.

The Australian Food and Grocery Council's (AFGC's) Product Information Form (PIF)²⁷ already includes lupin in a section called "Ingredients to be declared as allergens or sulphite". PIFs provide business customers with a comprehensive source of information on the food products sold to them. This form requests information on the food allergens present in the raw material and the potential for cross contact of the material.

Segregation processes already exist against cross contamination as lupin is a potential replacement for grains containing gluten. Growers that sell lupin directly to grain bulk buyers may be required to meet a receivable standard set by Pulse Australia.²⁸ This standard includes specifications such as the maximum amount of wheat that can contaminate the lupin (1 grain of wheat per ½ litre or 480 grams of lupin), the amount of green material that can be mixed in with the lupin and maximum moisture content. There is also a receivable standard for wheat that states a maximum amount of lupin permitted per unit of wheat. The conditions of these receivable standards help provide confidence to the primary processing industry e.g. those making wheat flour, that they do not need to worry about lupin contamination from the wheat supply itself.

Pulse Australia has only one receivables standard for lupin. This covers both lupin for stockfeed as well as that for human food. FSANZ has been informed that the industry is currently considering whether a separate receivables standard for lupin for human consumption should be developed.

Some organisations purchasing lupin especially for human consumption set stricter specifications. The outcomes of these stricter specifications include easier processing (more consistent grain size) and the potential to sell the lupin in the "gluten free" market.

²⁵ [Voluntary Incidental Trace Allergen Labelling \(VITAL\)](#) has been developed to provide a risk based methodology for food producers to use in assessing the impact of allergen cross contact and identify appropriate allergen precautionary labelling.

²⁶ Precautionary statement labelling is not regulated by the Food Standards Code.

²⁷ <http://www.afgc.org.au/publications/product-identification-form-pif/>

²⁸ Pulse Australia is a peak industry body that represents all sectors of the pulse industry in Australia, from growers and agronomists through to researchers, merchants, traders and exporters. It is unique in that it is an independent, non-political and whole of industry organisation, which acts as a catalyst for the development of the pulse industry.

Cross-contact and cross-contamination of lupin may occur where final foods or a mixture of products e.g. some containing lupin and some not, are being produced. Many lupin processors appear to be already aware of the allergenic potential of lupin.

2 The problem

The risk assessment undertaken by FSANZ, using internationally accepted criteria (WHO, 2002), concluded that lupin is an emerging food allergen of public health significance in Australia and New Zealand. As more products containing lupin become available (from Australia or from other geographical regions, such as Europe) the number of individuals in Australia and New Zealand experiencing allergic reactions to lupin is likely to increase.

The international criteria for evaluating whether a substance is a food allergen of public health significance utilise a weight-of-evidence type-approach, which takes account of:

- existence of credible cause and effect relationships
- reports of severe systemic reactions after exposure
- data on prevalence
- confirmation that an IgE-mediated reaction is involved
- potency of allergen in comparison with other known food allergens
- impact of processing on potency
- cross-reactivity with other known allergens.

The clinical data from Australia on lupin allergy fulfils the international criteria for significant new allergens. This information should be taken into account together with the likely increase of lupin in the food supply.

Clinical cases of allergic reactions to lupin in Australia were first reported in the scientific literature in 2004 (Smith *et al* 2004). Since these initial reports Smith has maintained a register of lupin-induced allergic food responses. Fourteen cases were recorded in the register, ten cases in South Australia and four cases in the Australian Capital Territory. In addition to these fourteen cases there have also been reports of at least ten individuals in Western Australia being allergic to ingested lupin (Goggin *et al*, 2008), and two recent medically confirmed anecdotal reports from Western Australia (personal communication). FSANZ is not aware of any other clinical data regarding reported incidences of lupin allergy in Australia. Nor is FSANZ aware of any clinically confirmed incidences of lupin allergy in New Zealand.

Australia and New Zealand have among the highest prevalence of allergic disorders in the developed world. An ASCIA-Access Economics Report¹⁴ estimated that in 2007, 4.1 million Australians (19.6% of the population) had at least one allergic disorder, with highest prevalence in the working age population, with 78% of those affected aged 15 to 64 years. It is predicted that from 2007 to 2050 the number of patients affected by allergic disorders in Australia will increase from 4.1 million (19.6% of the population) to 7.7 million (26.1% of the population). In a survey of 232 childcare centres and preschools in the ACT and central Sydney in 2006 (13,573 children enrolled), 6.6% were reported to have food allergy (2.1% allergic to peanut) (Loblay *et al.*, 2006).

Lupin belongs to the plants known as legumes and therefore contains proteins which are similar to those found in other legumes such as peanut and soy. Peanut and soy proteins are known to cause an allergic reaction in sensitised consumers. Hence proteins present in lupin will also be an allergen for some members of the community. The true prevalence of various food allergies in the population is uncertain.

However, prevalence estimates reported in the medical literature for peanut allergy range between 0.7 to 1.4% of the population in Australia and New Zealand. In view of the known immunological cross-reactivity between peanut and lupin antigens the number of people 'at risk' may be estimated from the prevalence of peanut allergies in Australia and New Zealand. If we assume 1.1% (an average of the reported range estimates) of the population then that would equate to around 250,000 individuals in Australia and around 50,000 in New Zealand. This estimate does not take into account situations in which lupin-specific proteins are the main allergens i.e. their immune system may not cross-react to peanut-specific protein or where allergy to lupin is associated with cross-reactivity with other legumes e.g. soy.

The number of people who are sensitive to lupin will be higher than those who are allergic, as sensitisation occurs before allergy and not all sensitised individuals will progress to allergy. The trigger(s) for progression from sensitisation to allergy is/are unknown, although based on the biology of allergy for susceptible individuals the greater the exposure i.e. the more a potentially allergenic food is consumed, the greater the chance a sensitised individual will convert to an allergic one. Once an individual has become sensitised there is a risk of becoming allergic, and once allergic to lupin in food they remain allergic. The most effective way to avoid allergy is to avoid food containing the allergen (EFSA, 2014). To allow the consumer to do this requires them to be aware that a food product contains the ingredient of concern.

Of the packaged products which use lupin or lupin products as ingredients that FSANZ is aware of, lupin is being declared in the ingredient list, so most (or possibly all) of industry is likely to already be compliant with the provisions of the proposed labelling changes to the Code. This will likely be due to the fact that lupin is present as an ingredient and is being listed in the ingredient list to meet the requirements in Standard 1.2.4, but also as a somewhat 'new' food, manufacturers may want to promote its presence. As far as we know it is not as yet being used as an additive or a processing aid (or an ingredient or component of these) in Australia and New Zealand but it is in overseas markets, and maybe in products imported into Australia or New Zealand (e.g. imported instant soup, instant Asian based meals, baked goods).

The problem is that not all food manufacturers would voluntarily and universally declare the presence of lupin in foods in the future (where lupin is not required to be declared in ingredient labelling) as usage grows and alternative uses are considered by manufacturers. This could lead to uncertainty for lupin-sensitive consumers since the presence of lupin in some foods would be declared while others would not. In the absence of more comprehensive information about the presence of lupin in foods, lupin sensitive individuals and their carers would be at risk.

The difference between the current ingredient labelling requirements which apply to lupins, compared to the mandatory declaration requirements for other allergens, is that allergen ingredients must be declared when present in the following manner (which is not currently the case for lupin ingredients):

- in a small package (less than 100 cm²),
- as an ingredient of a compound ingredient which makes up less than 5% of the food,
- as a food additive or processing aid (including when used as an ingredient or component of these), and
- where a food is not required to bear a label (e.g. when the food is unpackaged or is made and packaged on the premises).

Once diagnosed, the only treatment currently available for most individuals is prevention. Individuals need to adopt avoidance strategies, which usually consists of complete dietary exclusion of the problem food.

Such strategies are only effective if complete, accurate and understandable labelling of food is available. Emergency treatment strategies are available for those at risk of severe reactions, ranging from self-administered adrenalin and follow-up medical supervision, to admission to hospital. Allergy sufferers need to learn to identify and avoid products containing the problem foods, and what to do if any is accidentally ingested or if they experience symptoms of reaction.²⁹

Consequently, the economic impact of food allergy may be widespread and affect many sectors of society. A large population of individuals is likely to be affected, with associated costs to themselves, their carers and their households, potentially over a lifetime.²⁹

ASCIA-Access Economics Report (2007)¹⁴, estimates the value of lost wellbeing to be 73% of the total economic cost of allergies.

This DRIS examines the case for government intervention due to the serious health and safety outcomes of allergic reactions to lupin and the wellbeing (search³⁰ and avoidance³¹) costs incurred by those at risk attempting to avoid consumption. The actual risk of harm faced by the Australian and New Zealand population at this point in time is relatively small due to the present volumes of lupin in the food supply, but this has the potential to grow as lupin is increasingly consumed and used in different ways. The aim of the intervention would be to reduce allergic reactions but also to avoid higher than necessary search and avoidance costs incurred by those at risk. A legislative scheme may provide clearer assurance to these individuals and their family.

The purpose of the following analysis is to determine whether an appropriate non-regulatory or regulatory intervention exists to better manage potential public health and safety issues and related costs from consumption of lupin in a way that can be shown to be likely to result in a net benefit to the community as a whole.

3 Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- (a) the protection of public health and safety; and
- (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
- (c) the prevention of misleading or deceptive conduct.

FSANZ must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food; and

²⁹ Miles, S., Fordham, R., Mills, C., Valovirta, E., Mugford, M. A framework for measuring costs to society of IgE-mediated food allergy. *Allergy*. 2005;60:996–1003.

³⁰ Costs of search are the opportunity cost of time while benefits are derived from the extent to which information has a monetary value and a preventive health value, and the extent to which consumers regulate current diet. – Lawrence et al 1983

³¹ Search and avoidance cost are included in the total economic cost.

- (e) any written policy guidelines formulated by the Australia and New Zealand Forum on Food Regulation (the Forum).

The specific objective of this proposal is to manage potential public health and safety outcomes in relation to lupin products being available in Australia and New Zealand.

4 Options

In order to address the problem and achieve the stated objectives, this proposal considers three options.

4.1 Option 1 – Maintain the status quo

Consumers would rely on existing ingredient labelling requirements and voluntary labelling to inform them about the presence of lupin in food.

4.2 Option 2 – Prepare an industry code of practice

FSANZ, in partnership with relevant interested parties would develop a code of practice for food manufacturing industries.

4.3 Option 3 – Prepare a draft variation

Prepare a draft variation, so that a mandatory allergen declaration would be required on the label, or, where a label is not required, businesses would have to provide access to information about the presence of lupin in food being sold.

5 Impact analysis

5.1 Option 1 – Maintain the status quo

Under the status quo consumers would rely on existing ingredient labelling requirements and voluntary labelling to inform them about the presence of lupin in food.

Under this option, consumers with lupin sensitivity or allergies would not be able to ascertain in some circumstances whether food for sale contains lupin (e.g. if it was present in an unpackaged food, or being used as a food additive or processing aid, or an ingredient of a compound ingredient). Accordingly, there is a continued risk of these people having an allergic reaction, which may in a proportion of cases, be as severe as an anaphylaxis reaction (and could result in death). Alternatively they may continue to incur significant search and avoidance costs as they attempt to ensure food is lupin free.

The estimated value of lost wellbeing for allergy sufferers, including search and avoidance costs, is around \$6,551 per person per annum. If the financial cost is included, the cost is \$8,920 per person per annum.¹⁴ Individuals with allergies bear 48% of the financial costs, and their families and friends bear a further 1%. Federal government bears 32% of the financial costs; State and Territory governments bear around 5% of the costs, with the remaining 13% borne by others in society (including employers).

If the burden of disease (the economic cost of disability and premature death)³² is included, individuals bear 86% of the costs.

In Anaphylaxis Australia Inc.'s (2003)³³ survey³⁴, 81% respondents said that they did have to call food manufacturers for more information about the ingredients of their products and only 61% of those respondents indicated that they were satisfied with the response they were given on their most recent call.

Currently, food that contains lupin ingredients that are not declared would not trigger a recall³⁵. According to FSANZ recall data, in the last 10 years, there has been 204 allergen recalls in Australia.

5.2 Option 2 – Prepare an industry Code of Practice

A Code of Practice for food manufacturing industries could appropriately manage potential health and safety outcomes of lupin allergy in Australia and New Zealand. An industry Code of Practice would apply only to signatories to the Code of Practice and be voluntary with no legislation requiring relevant parties to comply with the recommendations.

As discussed in the section 1.4 above, The Australian Food and Grocery Council (AFGC) has prepared ***The Food Industry Guide to Allergen Management and Labelling***³⁶ that provides guidance for industry in managing and labelling food allergens currently listed in the section 1.2.3—4. This Guide is relevant to all sectors of the food industry involved in the supply, handling, production, distribution and sale of foods and encompasses members of the AFGC. It provides recommendations for the production and labelling of foods containing allergenic substances as listed in the Code. This guide provides:

- an overview of the mandatory allergen labelling requirements outlined in the Code
- an overview of the incidence and symptoms of food allergy and food intolerances and the substances in food that may provoke allergic reactions
- guidance on the control and management of allergens in the manufacture of foods
- information on testing for allergens
- guidelines for declaring mandatory and voluntary allergen information for foods
- an outline of VITAL (Voluntary Incidental Trace Allergen Labelling)³⁷.

The guide recommends a consistent approach in the presentation of allergen information to help allergic consumers more quickly and easily identify foods of concern, helping to minimise accidental consumption of unsuitable foods.

³² The disability, loss of wellbeing and premature death that result from allergic disease are more difficult to measure, but have been analysed in this chapter in terms of the years of healthy life lost, both quantitatively and qualitatively, known as the 'burden of disease', with an imputed value of a statistical life year (VSLY) so as to compare these costs with financial costs of allergy.

³³ Anaphylaxis Australia Inc (2003) Survey of members on product labelling, history of reactions and severity - accessed 3 April 2013

³⁴ The survey sample size was 245 members, 15 food allergic individuals and 230 family members of food allergic individuals. This additional information will be provided as a footnote in the report.

³⁵ Food recall – Action taken to remove from sale, distribution and consumption foods which may pose a safety risk to consumers'. A food recall may be initiated as a result of a report or complaint from a variety of sources – manufacturers, wholesalers, retailers, government agencies and consumers.

³⁶ <http://www.afgc.org.au/download/655/>

³⁷ [Voluntary Incidental Trace Allergen Labelling \(VITAL\)](#) has been developed to provide a risk based methodology for food producers to use in assessing the impact of allergen cross contact and identify appropriate allergen precautionary labelling.

FSANZ is advised the AFGC intends to amend the Food Industry Guide to Allergen Management and Labelling to include lupin. However, bakeries and other suppliers of foods that are not required to be labelled are not necessarily covered by or familiar with the AFGC guide – which mainly applies to labelled packaged food. Therefore, significant changes would have to be made to a current guide for it to provide equivalent guidance for lupin as the Code does for other allergens currently listed in the section 1.2.3—4 of the Code. Marginal cost of voluntary updating an existing allergen management framework for a medium size food manufacturing businesses is estimated to be around \$18,000 per business for upfront costs and ongoing compliance cost per year are estimated around \$52,000 per business.

An industry code of practice is not considered an appropriate risk management option for the following reasons:

- a non-regulatory option is not commensurate with the high level of risk to public health and safety
- as such, a non-regulatory option provides for:
 - limited business coverage and non-mandatory provisions leading to lower compliance; thereby
 - less comprehensive coverage of foods requiring declaration; and
 - less surety for consumers that all relevant food products are captured
 - increased wellbeing (search and avoidance) costs for consumers
 - potentially increased health care costs arising from allergic events
 - decreased quality of life for sensitive consumers
- A non-regulatory option would not trigger a recall if the presence of lupin ingredients in food is not declared.

As such, as a risk management measure it is considered inadequate because lupin, like any other allergen currently listed in the section 1.2.3—4 in the Code, presents high degree of risk for consumers.

Given industries' current labelling efforts there is likely to be little difference between the status quo and option 2 in terms of declaring the presence of lupin in ingredient labelling. The risk of this approach in comparison to status quo is that it could lead to increased confidence without increased compliance as consumers may be confused and expect this allergen to be regulated in the same way as all the other allergens. It could lead to higher level of risk for consumers since there is the prospect that that some foods will be voluntarily labelled appropriately while others would not. This is particularly so if lupin is used to source food additives and processing aids, as the level of diligence regarding the actual source is likely to be lower.

5.3 Option 3 – Prepare a draft variation

This option involves preparation of a draft variation, with a 12-month transition period, to include lupin and lupin products in Section 1.2.3—4 of the Code so that mandatory allergen declaration requirements apply; and to include lupin in Schedule 10 so that the specific source name of lupin oil is required. This would mean that for foods that require a label (including small packages), where lupin is used in food as an ingredient (or within a compound ingredient), an additive or as a processing aid (or an ingredient or component of these), the label would have to declare the presence of lupin. Where a label is not required (e.g. where the food is unpackaged or is made and packaged on the premises such as a bakery or restaurant), consumers would have access to information about the presence of lupin either in connection with the display of the food or provided to them on request.

The health benefits of Option 3 for consumers arise from ease in identifying the presence of lupins afforded by the more comprehensive labelling under the proposed variation to Standard 1.2.3, compared with the (limited) ingredient labelling that is required by Standard 1.2.4. Further benefits arise for consumers from the recall procedures that would apply were labelling found to be non-compliant under Standard 1.2.3. This would not be the case for options 1 and 2. This option would also be of potential value to people who have other food based allergies, particularly peanut and soy allergies due to the potential for cross-reactions between these allergens.

Australia and New Zealand were among the first countries to recognise the need to regulate food allergens with the introduction, in 2002, of mandatory declaration requirements in the Code. Therefore, food manufacturers, food retailers and the food service sector should already have allergen management arrangements in place.

Those businesses would have incurred the following costs in setting up their existing allergen management arrangements:

- develop allergen management procedures
- cleaning of premises, equipment and tools
- raw materials handling
- equipment and production scheduling
- labelling of raw materials and semi-finished goods
- staff training
- labelling finished products.

The marginal cost of updating an existing allergen management framework for a medium size food manufacturing businesses is estimated to be around \$18,000 per business and ongoing compliance cost per year around \$52,000 per business.

As far as FSANZ is aware, packaged labelled products in Australia and New Zealand using lupin or lupin products as ingredients are declaring lupin in the ingredient list to meet the requirements of Standard 1.2.4. In the case where foods are not required to bear a label (e.g. unpackaged foods, or foods that are made and packaged on the premises such as a bakery or restaurant), although declaration of ingredients is not currently mandatory, FSANZ is aware of situations where the use of lupin as an ingredient is declared to consumers. Therefore, based on currently available information, FSANZ is of the view that current declaration of lupin is very high and that there would be minimal impact of the draft variation on current primary users of lupins. New companies or new uses of lupins in the Australia New Zealand food supply would incur start-up costs however, with the event of Proposal P1026 there would be prior knowledge of this and costs built into product development.

FSANZ is unaware of any evidence demonstrating commercial disadvantage to products as a result of lupin ingredient labelling. Whether the need to also apply the labelling required under the proposed variation would impede market expansion is unknown. The draft variation is not a warning statement, it simply serves to more comprehensively indicate the presence of lupin where used in food additives, compound ingredients etc. and foods not required to bear a label. FSANZ considers that proportion of population that would benefit from consuming lupin is much higher than proportion that is allergic to lupin. Therefore, the net benefits of this approach outweigh the small likelihood of any commercial disadvantage brought about by such labelling.

In comparison to the status quo this option would reduce confusion and search and avoidance costs, and provide more certainty for consumers and improve their wellbeing. Therefore, Option 3 is risk-proportionate and appropriate, low cost way to manage a new food allergen.

Although current declaration of lupin is very high, it is very important to adopt the proposed approach for the future due to the growing use of lupin and uncertainty of future voluntary labelling. Also, including lupin in the list of allergenic foods requiring declaration under Standard 1.2.3 is expected to improve awareness of lupin allergy and provide more confidence for sensitive individuals that food product information provided is comprehensive.

Lupin sensitive individuals rely on the comprehensive coverage of allergen declarations to help them avoid lupin and therefore avoid repeated adverse health conditions associated with the consumption of lupins. If that information is not available or if they do not have trust in the food supply their search and avoidance will grow and that will have a significant impact on their wellbeing and total financial cost.

5.4 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 (RBM) framework. The RBM calculates the compliance costs of regulatory proposals on business, individuals and community organisations using an activity-based costing methodology.

FSANZ used the RBM to estimate a marginal cost of updating an existing allergen management framework for a medium size food manufacturing businesses. Upfront costs are estimated to be around \$18,000 per business and ongoing compliance cost per year around \$52,000 per business. Currently, around five medium size businesses³⁸ are using lupin as an ingredient in their products. Therefore, total marginal upfront costs for impacted medium size businesses are estimated to be around \$88,000 and total marginal ongoing compliance costs for impacted medium size businesses are estimated to be around \$262,000 per year.

5.5 Comparison of options and conclusion

FSANZ concludes that due to the serious nature of the risk to human health, Option 3 (Prepare a draft variation) is the preferred option to address the public health and safety outcomes of allergic reactions to lupin in the Australia and New Zealand populations.

It is recognised that there could be costs to industry arising from a regulatory option. As noted above, FSANZ estimates that the compliance costs of managing an additional allergen could be around \$18,000 for upfront costs and \$52,000 for ongoing costs. The only difference between compliance cost of option 2 and option 3 are ongoing business-incurred audit costs that are estimated to be around \$1000 per year.

Upfront costs of implementation are estimated to be around \$28,400 per jurisdiction - \$20,000 for staff training and \$8,400 for integrating new regulation into their administrative procedures. However this is presumably an overestimate as it is most likely adding an additional allergen to an existing allergen management framework rather than implementing a new procedure.

The estimated financial cost of food allergy is around \$2,369 per person per annum. If the value of lost wellbeing is included, the cost is \$8,920 per person per annum.¹⁴ The proposed option is unlikely to completely mitigate these costs.

³⁸ FSANZ internal research

However, FSANZ considers that these costs are outweighed by the benefits to consumers. These benefits arise from the reduced number of adverse health reactions associated with consumption of lupin and lupin products and reduced financial and wellbeing costs to lupin sensitive individuals.

As Australia and New Zealand have among the highest prevalence of allergic disorders in the developed world it is very important to have a comprehensive coverage of food allergen declarations to reduce the number of adverse health conditions associated with consumption of lupin and lupin products, to help consumers reduce search and avoidance cost and to help improve their quality of life

The benefit of Option 3 is that at-risk individuals are better able to avoid lupin and therefore avoid repeated adverse health conditions associated with the consumption of lupins. It would help reduce the financial cost for lupin sensitive individuals and significantly improve their wellbeing as it would be much easier for them to find information about the presence of lupin ingredients in labelled and unlabelled food. This option would also be of potential value to people who have other food based sensitivities, particularly peanut and soy allergies due to the potential for cross-sensitivity between these allergens.

6 Consultation

6.1 Targeted consultation

From the commencement of this Proposal, FSANZ has made considerable efforts to engage with the lupin 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 lupin industry and develop better regulation.

In September 2013, a targeted consultation was conducted seeking data and/or information on the likely costs and possible benefits if lupin was regulated as a food allergen to require mandatory allergen declaration consistent with current allergens identified in the Code. Identified businesses were approached via email. Separately, FSANZ was also able to link into a survey that the AFGC conducted on their PIFs which are now widely used in the Australian and New Zealand food industry. The AFGC PIF survey included some questions relating to lupin and FSANZ was able to follow up with companies using its slightly amended lupin questionnaire for food manufacturers. FSANZ received 10 responses.

In December 2014, FSANZ visited an ingredient manufacturer in NSW and four primary producers of lupin and lupin-derived products in WA to gain information on the supply chain and current practices. FSANZ sought further information and feedback from industry, consumers and other stakeholders through the call for submissions process.

Further targeted consultation with Australian Food and Grocery Council, Allergy and Anaphylaxis Australia and a spokesperson for a lupin food company was undertaken to discuss issues raised during the public consultation period, 16 June 2016 to 28 July 2016.

6.2 Summary of issues raised in submissions

Fourteen submissions were received to the Call for Submissions from the following organisations (Attachment 1):

- Grain Trade Australia
- Department of Health WA
- Department of Agriculture and Food

- New Zealand Food & Grocery Council
- Ministry for Primary Industries
- NSW Food Authority
- Allergy & Anaphylaxis Australia
- Grains Industry Association of Western Australia
- Department of Health & Human Services Vic
- Sanitarium Health & Wellbeing
- The Grains & Legumes Nutrition
- Allergen Bureau
- Food & Beverage Importers' Association
- Australian Food & Grocery Council.

Many issues were raised in these submissions, not all of which are relevant to this DRIS.

All fourteen submitters supported the proposed draft variation in the Code. One submitter supported both an industry code of practice and draft variation.

Submitters that supported a regulatory option agreed that there were public health and safety outcomes of allergic reactions to lupin in the Australia and New Zealand population and that lupin should be added to the list of mandatory allergens. The objectives of this would be to reduce the number of adverse health conditions associated with consumption of lupin and lupin products and reduce financial and wellbeing costs to lupin allergic individuals.

Four submitters asked for the extension of the proposed transition period from 12 months to 18 months or more. Given potentially serious health and safety outcomes of allergic reactions to lupin and the fact that industry has been aware of this proposal since 2013, FSANZ has decided not to extend the proposed transition period of 12 months.

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. A submission was received from the US Food and Drug Administration correcting an editorial error made in the Call for Submissions in respect of the US regulations for allergen declarations. As most of the imported lupin products come from Europe and as Europe already has mandatory lupin declaration requirements, any changes required would be integral to the changes already necessary to comply with Australian and/or New Zealand labelling laws generally.

7 Implementation and review

The draft variation would commence 12 months from the date of gazettal. Relevant parties have been kept informed of this proposal and can make appropriate commercial decisions to minimise the cost.

Upfront costs of implementation are estimated to be around \$28,400 per jurisdiction - \$20,000 for staff training and \$8,400 for integrating new regulation into their administrative procedures.³⁹ However this is presumably an overestimate as it is most likely adding an additional allergen to an existing allergen management framework rather than implementing a new procedure.

³⁹ FSANZ internal research – costs provided by jurisdictions for the Government Cost model

State and territory regulatory agencies (Australia) and the Department of Agriculture and Water Resources and the Ministry for Primary Industries (New Zealand) would be responsible for managing the implications of the inclusion of lupin and lupin products in section 1.2.3—4.

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Attachment 1 – Summary of submissions and FSANZ response

There were fourteen submitters on the draft variation and the key issues raised are identified in Table 1: Summary of Issues below along with the FSANZ response. The issues raised include, mandatory versus voluntary approaches, labelling considerations, transition period, analytical issues, and inadvertent presence of lupins

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
Labelling exemptions for highly refined lupin products – consistent with recent allergen labelling exemption granted under P1031, consideration should be given to lupin products that have been degummed, neutralised, bleached and deodorised	Allergen Bureau	Exemptions for highly refined lupin products have not been considered in the scope of this project. FSANZ is not aware of suitable evidence for exempting such products at this point in time.
Include a clarification statement in the Approval Report to advise that co-mingling of grains (including Lupin) does not trigger mandatory labelling, but manufacturers should utilise a precautionary labelling system, such as that provided by VITAL	Allergen Bureau	<p>The presence of lupin as an ingredient, ingredient of a compound ingredient, food additive or processing aid (or an ingredient or components of these), will need to be declared under the mandatory requirements.</p> <p>Voluntary precautionary statements made by a food manufacturer are not generally regulated by the Code. Food manufacturers will need to decide whether to use a precautionary labelling system such as VITAL.</p>
Analytical sensitivity – the use of two lupin assays with different cross-reactivity profiles may be needed to avoid false positives eg with soy and chickpea	Allergen Bureau	See section 2.3.3. ELISA kits are available that will detect lupin. FSANZ acknowledges that some commercially available kits may vary with reactivity to different lupin species and cross-reactivities to other legumes. However, the onus remains on analytical laboratories to validate the kits with the food matrix being analysed. FSANZ understands this is standard industry practice.
The Approval Report should note that manufacturers who apply the AFGC Best Practice Allergen Labelling Guidelines will need to change their labels.	Allergen Bureau	Noted

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Some concerns that requirement to label lupin may undermine the commercial viability of a newly developing industry.</p>	<p>Grains Industry Association of Western Australia</p>	<p>Evidence available to FSANZ is that packaged products using lupin or lupin products as ingredients are already declaring lupin in the ingredient list to meet the requirements of Standard 1.2.4 (statement of ingredients). FSANZ is also unaware of any evidence demonstrating commercial disadvantage to the products as a result of this. The variation serves to address comprehensively the presence of lupin when used in food additives, compound ingredients etc and unlabelled foods. FSANZ considers the net benefits of this approach outweigh the cost and any commercial disadvantage brought about by more comprehensive labelling. See section 2.4 below.</p>
<p>A&AA remains concerned by FSANZ's priorities in addressing shortcomings of standard 1.2.3—4, which in many cases remain unresolved.</p> <p>A&AA strongly encourages FSANZ to communicate directly with the peak medical body, the Australasian Society of Clinical Immunology and Allergy at the outset of new projects in order to prioritise the magnitude of the problem, compared with other food allergen labelling issues that need attention.</p> <p>Whilst there was some discussion five or more years ago on the possible increase in individuals with lupin allergy because of potential cross reactivity in those with peanut allergy, anecdotally this does not seem to have become apparent. That said, now that FSANZ has spent years and resources investigating the lupin issue, it would seem ludicrous to not include lupin, which is easily hidden in baked goods, as a major allergen.</p>	<p>Allergy & Anaphylaxis Australia</p>	<p>Noted.</p> <p>FSANZ considers the focus on lupins at this time to be appropriate. See section 2.2.</p> <p>Broader allergen labelling issues are being addressed by FSANZ as part of Proposal P1044.</p> <p>FSANZ sought the advice of its Food Allergy and Intolerance Advisory Group, whose membership includes expert clinicians from Australia and New Zealand. Organisations such as A&AA and the Australasian Society of Clinical Immunology and Allergy, and the Allergen Collaboration are also able to make their views and any concerns known to FSANZ at any time.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Due to standard sampling and delivery procedures GTA members cannot guarantee grain sold for domestic consumption is totally free of lupin seed or lupin seed material and it is uneconomic for all grain to be guaranteed as such. GTA requests no mandatory labelling unless lupin is used as an ingredient, food additive or processing aid.</p>	<p>Grain Trade Australia (GTA)</p>	<p>Mandatory labelling requirements will apply when lupin is present in food as an ingredient, ingredient of a compound ingredient, food additive or processing aid (or an ingredient or component of these).</p> <p>However, where there is uncertainty regarding the absence of lupin in food products or grain supplies, it will be up to food processors and manufacturers to manage the risk accordingly.</p> <p>FSANZ also understands from businesses the need to assure niche markets afforded by the use of lupin (such as gluten free) will drive suitably rigorous specifications for ingredient supplies.</p>
<p>Has consideration been given to honey derived from lupin, and possible issues of allergenicity arising from this.</p>	<p>New Zealand Ministry for Primary Industries (MPI)</p>	<p>FSANZ is unaware of any published literature demonstrating the presence of the allergenic protein in pollen, or reports of incidences of food allergy attributed to consumption of honey derived from lupins.</p> <p>To establish whether or not the honey bees have collected pollen from lupin flowers would require sophisticated analysis that cannot be performed on a routine basis.</p> <p>Furthermore FSANZ notes that to date reports of incidences of lupin allergy have arisen from the consumption of foods derived from lupin seeds rather than honey, and there are no case reports of clinical reactions to ingestion of trace amounts of lupin.</p>
<p>Suggest self-revocation clauses for transitional arrangements so that after transition these (i.e. clause 2.2) no longer appear in the Code. If this is addressed by other means this should be noted in the Approval Report</p>	<p>MPI</p>	<p>The FSANZ Act provides for Minor Procedure Proposals as a means to remove Code provisions that have ceased to have effect. Reliance on this expedited procedure enables simpler and clearer provisions and requirements, particularly for stakeholders. The intent is that the Code will be amended to remove sections 1.2.3—1A and S10—1A after they cease to have effect (i.e. once the prescribed transitional period expires). This will occur by means of a code maintenance proposal.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Association of Analytical Communities is developing a reference method for lupin. Australian laboratories are not currently NATA accredited for lupin testing. It is unknown whether non-European importers have facilities for lupin testing.</p>	<p>New South Wales Food Authority</p>	<p>Advice from analytical laboratories confirms that ELISA kits are available to detect lupin (see section 2.3.4)</p> <p>Development of NATA accreditation is demand driven. NATA accreditation will increase with the need for lupin analysis.</p>
<p>Costs to industry and government have been inadequately addressed and are likely to be underestimated</p>	<p>New South Wales Food Authority</p>	<p>FSANZ does not accept that such costs have been inadequately addressed or underestimated in its assessment. See in this regard, section 2.4 and the Decision RIS at Attachment C. The Decision RIS was subject to independent assessment by the Office of Best Practice Regulation.</p> <p>FSANZ adopted a cautious approach in estimating cost. For example, upfront costs of implementation to government are estimated to be around \$28,400 per jurisdiction - \$20,000 for staff training and \$8,400 for integrating new regulation into their administrative procedures. However such costs may well be less given that the change involves adding one additional allergen to an existing allergen management framework rather than implementing a new procedure. Due regard was also given to the increased need for and cost of food testing and analysis for compliance purposes.</p> <p>The cost to government and industry of this measure was taken into account by FSANZ. However, FSANZ considers that these costs are outweighed by the benefits to consumers due to reduced number of adverse health reactions associated with consumption of lupin and lupin products and reduced financial and wellbeing costs to lupin sensitive individuals.</p> <p>The estimated financial cost of food allergy is around \$2,369 per person per annum. If the value of lost wellbeing is included, the cost is \$8,920 per person per annum.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Concerned re regulation being implemented in the context of lack of data and a not overly significant health and safety impact. Supports Option 2⁴⁰ for New Zealand’s purposes but recognises need for trans-Tasman consistency. Thereby, supports adoption of Option 2 only, or Options 2 and 3 with the implementation of Option 3 (regulation) in place for adoption at a future date, based on evaluation of the uptake by industry, and lupin allergen incidence.</p>	<p>New Zealand Food and Grocery Council</p>	<p>For the reasons outlined in this report, FSANZ considers Option 3 and the approved variation to be warranted. The severity and potential risk of allergenic reactions requires a proportionate risk management approach. See sections 2.2., 2.3, 2.4., Attachment C and SD1.</p>
<p>Industry should be encouraged to develop a Receivables Standard (RS) for lupin for human consumption.</p>	<p>Victorian Departments of Health and Human Services; Development and Economic Development, Jobs, Transport and Resources</p>	<p>Noted, however outside FSANZ area of responsibility. Industry demand for superior specifications for lupin grains to be used in niche market food products will drive appropriate Receivables Standards</p>
<p>Advice is sought on how lupin can be tested for compliance purposes</p>	<p>Victorian Departments of Health and Human Services; Development and Economic Development, Jobs, Transport and Resources</p>	<p>Further detail provided in section 2.3.4.</p>
<p>There is an error in the second sentence at the top of page 6. The US FDA does NOT require any special allergen labelling for lupin or lupin-derived ingredient</p>	<p>United States Food and Drug Administration</p>	<p>Noted, corrected in Approval Report</p>

⁴⁰ Option 1 – status quo, Option 2 – voluntary measures, Option 3 – regulatory approach

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Transition period - should be extended from 12 months to 18 or 24 months. Manufacturers require additional time to gather information on potential issues of cross-contamination.</p>	<p>Australian Food and Grocery Council (18 months) Food and Beverages Importers Association (18 months) Grains and Legumes Nutrition Council (18 months) Sanitarium Health & Wellbeing (24 months)</p>	<p>Not accepted. FSANZ considers it inappropriate to extend the 12 month transition period given the matter at hand is an allergen.</p>
<p>No issues of concern raised</p>	<p>Western Australian Department of Food and Agriculture</p>	