



COAG Decision Regulation Impact Statement – Proposal P1026

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)¹.

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 allergygo

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 Report² estimates the financial cost of allergies in Australia to be around \$9.7 billion per annum.³ 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)

¹ [Food Standards Code](#), FSANZ website

² [ASCIA-Access Economics Report \(2007\)](#). Please note these cost have been indexed to 2016 using [ABS Cat. No. 6401.0, Consumer Price Index](#).

³ We could not find any reports on the economic or financial cost of allergies in New Zealand

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 research⁴ 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 anaphylaxis⁵. 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. 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

⁴ [Supporting document 3](#) - Rapid evidence assessment on consumer understanding, attitudes and behaviour with respect to food allergen labelling

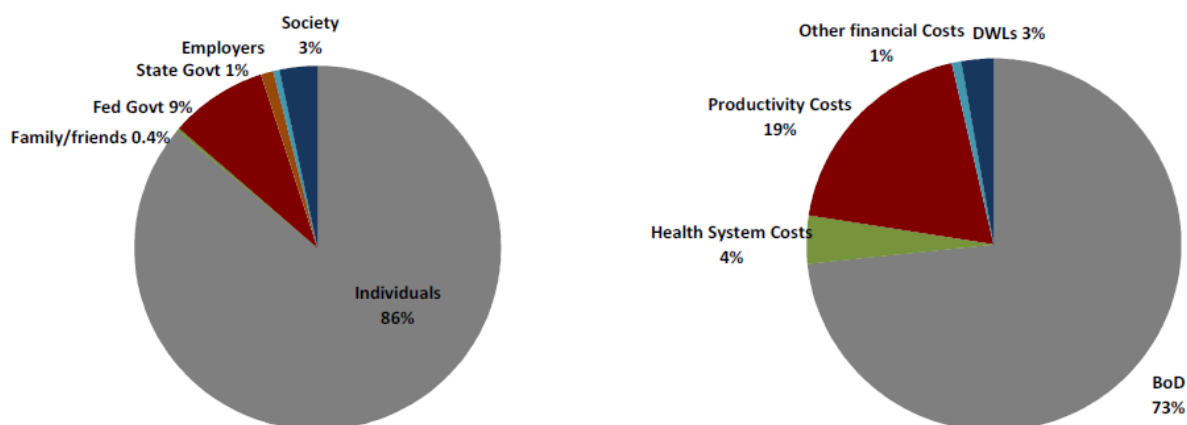
⁵ Kemp, AS and Wu W (2008) Food allergy and anaphylaxis – dealing with uncertainty. *Medical Journal of Australia*, 188 (9):503-504

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 Report², estimates financial cost⁶ of around \$2,369 per person with allergies per annum. Including the value of lost wellbeing, the economic cost⁷ 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)⁸ 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)²



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. The

⁶ Total financial costs comprise both direct medical costs and the indirect costs of lost productivity and the deadweight costs of additional taxation.

⁷ 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.

⁸ 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.

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 Australia⁹ 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. Although lupin allergy is commonly seen in association with peanut allergy, it is equally common in children sensitised to tree

⁹ Loblay et al, 2009-unpublished data

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)¹⁰. 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.¹¹ 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. These food products are mainly used where lupin flour has been added to wheat flour to produce baked goods. Use

¹⁰ [Food Standards Australia New Zealand \(FSANZ\) - Review of the regulatory management \(2010\)](#)

¹¹ [Western Australian Department of Agriculture and Food, 2014](#)

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***¹² 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 AGFC. It provides recommendations for the production and labelling of foods containing allergenic substances as listed in the Code.

¹² [Food Industry Guide to Allergen Management and Labelling report](#)

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)¹³.

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 basis¹⁴ 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)¹⁵ 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.¹⁶ 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

¹³ [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.

¹⁴ Precautionary statement labelling is not regulated by the Food Standards Code.

¹⁵ [Product Identification form](#), Australian Food & Grocery Council

¹⁶ 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.

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. 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 Report² 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.¹⁷

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.¹⁷

ASCIA-Access Economics Report (2007)², 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 (search¹⁸ and avoidance¹⁹) 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.

¹⁷ 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.

¹⁸ 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

¹⁹ Search and avoidance cost are included in the total economic cost.

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
- (e) any written policy guidelines formulated by the Ministerial Council (now the Council of Australian Governments Legislative and Governance 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.² 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.

In Anaphylaxis Australia Inc.'s (2003)²¹ survey²², 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 recall²³. 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***²⁴ that provides guidance for industry in managing and labelling food allergens currently listed in the

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.

²¹ Anaphylaxis Australia Inc (2003) Survey of members on product labelling, history of reactions and severity - accessed 3 April 2013

²² The survey sample size was 245 members, 15 food allergic individuals and 230 family members of food allergic individuals.

²³ 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.

²⁴ [Food Industry Guide to Allergen Management and Labelling report](#)

section 1.2.3—4 of the Code. 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 AGFC. 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)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.

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 of the Code, presents high degree of risk for consumers.

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.

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 businesses²⁶ 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.

²⁶ FSANZ internal research

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.² The proposed option is unlikely to completely mitigate these costs.

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.²⁷ 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.

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 of the Code.

²⁷ FSANZ internal research – costs provided by jurisdictions for the Government Cost model

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Attachment 1 - Summary of submissions and FSANZ response

There were fourteen submitters to Proposal P1026 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	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.
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.</p> <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>Allergy & Anaphylaxis Australia (A&AA)</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 2²⁸ 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>

²⁸ 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>	