



Supporting Document 2

COAG Consultation Regulation Impact Statement – Proposal
P1026

Lupin as an Allergen

Executive summary

This Consultation Regulation Impact Statement (RIS) has been prepared for Proposal 1026 – Lupin as an allergen. The RIS provides a preliminary examination of the options available for managing potential health and safety outcomes of allergic reactions to lupin in the Australia and New Zealand population.

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 an 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 within 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 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 allergy 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.

Lupin is an emerging food allergen of public health significance in Australia. However, its presence in food may not always be declared to consumers and therefore its extent of use is not known. Other major food allergens listed in the Code (wheat, crustacea, egg, fish, milk, peanuts sesame seeds, soybeans, tree nuts and 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) in connection with the food or provided on request, meaning at risk consumers can avoid their consumption.

This consultation RIS considers three options for addressing the problem:

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.

FSANZ undertook targeted consultation with industry in 2013 and 2014. This work has informed the development of the options explored in this Consultation RIS as well as the analysis of the impacts of each option. However, collected information was not sufficient to establish the full scope and nature of this industry or the true level of allergic or sensitized individuals in Australia and New Zealand.

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1 Introduction

This Consultation Regulation Impact Statement has been prepared to provide a preliminary 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.

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

- a statement of the problem – explaining the need for government action
- a statement of the objectives of any intervention
- a statement of the possible options to address the problem
- an impact analysis of the options
- details of the consultation undertaken

FSANZ is seeking information from stakeholders on a range of issues in relation to the options set out in this RIS.

In addition, we would welcome any general comments, data or information on the proposed options. Information collected will be used to prepare a Decision RIS that will be presented to decision makers and also be made publicly available. If information of sufficient quality and volume can be obtained from submissions, it may be possible to undertake a more quantitative impact analysis of the proposed options for this document.

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.

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.

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 another food (e.g. peanuts) and because of similarities between the proteins in another food (e.g. lupin), they develop allergy to that other food as well (in this case lupin). It should be noted not all people with allergy to the first food will become allergic 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.

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).

The most 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, so the likelihood of consumers encountering new food allergens increases.

Allergy experts estimate the population with food allergy to be 10–20 fold higher than the population who experience anaphylaxis¹. 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 different severity of reaction on different occasions. The reason for this variation is 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 involved. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are the main risk management tools available 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 key. Similarly EFSA (2014) conclude that dietary avoidance is a mainstay for management of food allergy. Declaring allergens on packaged labels and requiring this information to be available for unpackaged foods is seen as an effective risk management tool in the avoidance of food allergy in susceptible consumers.

1.1.1 Lupin as a Food Allergen

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)². 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 Consultation RIS is part of that Proposal.

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 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.

¹ Kemp, AS and Wu W (2008) Food allergy and anaphylaxis – dealing with uncertainty. Medical Journal of Australia, 188 (9):503-504

² [Food Standards Australia New Zealand \(FSANZ\) - Review of the regulatory management \(2010\)](#)

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, difficult 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 dose. 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.

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 Australia³ 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 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.

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. 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. 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 the potential health benefits spreads.

³ Loblay et al, 2009-unpublished data

Western Australia (WA) accounts for the majority of Australian lupin production and exports.⁴ 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 is consumed each year in Europe. These food products are mainly 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 factors such as:

- perceived nutritional benefits due to higher protein and fibre content compared with commodities such as soy, wheat, chickpeas, and lower fat content than soy
- it can be a more cost-effective alternative to ingredients such as soy
- it is gluten free
- it is GM free - no GM lupin is produced in Australia or New Zealand.

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 much 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 milk substitute.

The development of lupin as a human food in Australia and New Zealand has been relatively slow for the following reasons:

- low price of lupin in recent years – this has resulted in farmers switching to other rotational crops such as GM canola
- lack of awareness - feedback from various FSANZ questionnaires indicated that few consumers and food manufacturers are aware of lupin as a potential human food commodity
- lack of distribution – lupin production is concentrated in WA, with most processing also occurring there. The expense of road transport to areas distant from WA, such as Eastern Australia, for incorporation into human food products is prohibitive
- consumer understanding of allergenicity - information received by FSANZ suggests that some lupin businesses are concerned that the consumer understanding of

⁴ [Western Australian Department of Agriculture and Food, 2014](#)

allergens is low e.g. some consumers confuse allergens with toxins. This lack of understanding may discourage such consumers from purchasing products containing lupin.

1.3 The current regulatory arrangements

The current food allergen management framework was set in 2002 and it has been supported and accepted by government and industry.

Food sold in Australia and New Zealand is required to declare the presence of certain foods or substances listed in section 1.2.3—4. In accordance with Standard 1.2.1 – Requirements to have labels or otherwise provide information), 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. These requirements have been in place since December 2000 when the Code first came into effect.

Lupin is not currently listed in section 1.2.3—4 of Standard 1.2.3. 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'. If lupin was added to the list in section 1.2.3—4, it would also be proposed that oil derived from lupin would be added to Schedule 10 – Generic names of ingredients and conditions for their use.

The use of lupin as an ingredient in food is currently subject to 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).

There are packaged products in Australia and New Zealand that currently declare the use of lupin as an ingredient in the statement of ingredients. This allows consumers who may be allergic to identify lupin and make informed purchasing decisions. However, 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 is supplied in a restaurant or catering establishment), do not have to declare lupin in an ingredient list making it difficult for consumers who may be allergic to lupin to make informed purchasing decisions.

Potential further uses of lupin in food products in Australia and New Zealand could also lead to instances where the presence of lupin is not 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 allergic to identify lupin and make informed purchasing decisions.

1.4 Industry practices

Food manufacturers can choose to provide precautionary allergen labelling⁵. Such labelling is voluntary and is not regulated in the Code.

The Australian Food and Grocery Council’s (AFGC’s) Product Information Form (PIF)⁶ 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 it is replacement for grains containing gluten. Growers that sell lupin directly to grain bulk buyers are required to meet a receivable standard set by Pulse Australia.⁷ 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

⁵ A food allergen precautionary statement is a declaration of the possible inadvertent presence of an allergen in the food (e.g. a ‘may contain’ statement). Precautionary statements are made by food manufacturers and importers on a voluntary basis.

⁶ <http://www.afgc.org.au/publications/product-identification-form-pif/>

⁷ 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 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 allergenicity 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 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). 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 Report⁸ estimated that in 2007, 4.1 million Australians (19.6% of the population) had at least one allergic disease, 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 diseases 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 allergy 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

⁸ ASCIA-Access Economics Report (2007)
http://www.allergy.org.au/images/stories/pospapers/2007_economic_impact_allergies_report_13nov.pdf

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.

All packaged products that FSANZ is aware of declare the use of lupin in the ingredient list, so most (or possibly all) of industry is likely to already be compliant with the major provisions of the proposed labelling changes to the Code. This is probably due to the fact that lupin is somewhat 'new' and novel meaning that manufacturers want to promote its presence. It is not as yet being used yet 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.

The risk is that not all food manufacturers may voluntarily and universally label (packaged and unpackaged) goods in the future as usage grows and alternative uses are considered by manufactures. This could lead to uncertainty for consumers since some foods would be labelled while others would not. In the absence of reliable and mandated information about the presence of lupin in foods, lupin allergic patients and their carers would be at risk. In addition to some avoidable health and welfare costs the absence of reliable labelling would most likely lead to significant avoidance and/or search costs for a percentage of the population meaning in many instances the avoidance of manufactured food.

In Anaphylaxis Australia Inc.'s (2003) survey, 98% respondents said that they were very unlikely to purchase a food product with no ingredient label for food allergic individuals.

This RIS examines the case for government intervention due to the serious health and safety outcomes of allergic reactions to lupin and the search and avoidance 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 has the potential to grow if lupin is increasingly consumed and is used in different ways. However, higher than necessary search and avoidance costs may be still being incurred by those at risk and 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 or 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

The primary objective is to provide for efficient and effective public health and safety outcomes in relation to lupin products being available in Australia and New Zealand. FSANZ is required to meet three primary objectives:

- (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)).

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 the food they purchased contains lupin (e.g. if it was present in an unpackaged food, or being used as a food additive or processing aid). 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), to

undeclared presence of lupin. Alternatively they may continue to incur significant search⁹ and avoidance costs as they attempt to ensure their food is allergen free.

Stakeholders views are sought on the merits of this approach and in particular on the following:

- Are there any other costs or benefits that should be taken into account in considering the status quo?
- What are the costs (health, economic and financial) to at risk (sensitive or allergic) consumers associated with an allergic reaction to lupin?
- What costs are at-risk consumers currently incurring (and likely to incur) in seeking out information about potential presence of lupin in food?

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 be voluntary with no legislation requiring relevant parties to comply with any recommendations.

The Australian Food and Grocery Council (AFGC) has prepared ***The Food Industry Guide to Allergen Management and Labelling***¹⁰ that provides guidance for industry in managing and labelling food allergens.

The Guide is relevant to all sectors of the food industry involved in the supply, handling, production, distribution and sale of foods. It provides recommendations for the production and labelling of foods containing allergenic substances as listed in the Food Standards 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)¹¹.

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.

⁹ 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 at al 1983

¹⁰ <http://www.afgc.org.au/download/655/>

¹¹ <http://allergenbureau.net/vital/vital-downloads/>

The guide also talks about precautionary statements which are made by food manufacturers and importers on a voluntary basis and are appropriate when, despite all reasonable measures, the inadvertent presence of allergens in food is unavoidable.

The Food Industry Guide to Allergen Management and Labelling could be amended to include lupin. This could involve providing a recommendation that in addition to mandatory food allergens, lupin should also be declared on the label. However, bakeries and other suppliers of unpackaged foods are not necessarily covered by or familiar with the AFGC guide – which mainly applies to packaged food.

In Anaphylaxis Australia Inc.'s (2003)¹² survey, 98% respondents said that they were very unlikely to purchase a food product with no ingredient label for food allergic individuals. An industry code of practice is not considered an appropriate risk management option for the following reasons:

- an industry code of practice is not appropriate to mitigate a potentially serious health and safety outcomes of allergic reactions to lupin
- failure to comply could be particularly hazardous if, in light of existing allergen management framework, allergy sufferers purchase food more confidently, believing that allergen information will be complete and correct
- non-compliance with an industry code of practice would not be considered a criminal offence.
- this option may not reduce search and avoidance costs if consumers do not have confidence in the system.

Given industries present labelling efforts there is likely to be little difference between the status quo and option 2. 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 risk in the future that some food would be labelled appropriately while others would not.

Stakeholder views are sought on the merit of this approach and in particular:

- What is the likelihood of industry wide participation in a voluntary code?
- Would a voluntary code lead to greater confusion and more risk for consumers?
- Would this approach be adequate to get coverage of unpackaged foods?
- Would a voluntary code provide an allergic/sensitive individual or carer with sufficient assurance?
- How many, or what percentage of allergic reactions to lupin could be avoided under option 2?
- What are the costs associated with the implementation of an industry code of practice?

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 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, where lupin is used

¹² Reproduced from: Anaphylaxis Australia Inc (2003) Survey of members on product labelling, history of reactions and severity.
<http://www.allergyfacts.org.au/images/pdf/AAI%20Food%20Labelling%20Survey%202003.pdf>, accessed 3 April 2013

in food as an ingredient (or 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), 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 benefit of this option is that at risk individuals are better able to avoid lupin and therefore avoid adverse health conditions associated with their consumption. It would help to minimise search and avoidance costs. 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 already have allergen management plans/programmes in place.

Those businesses would have incurred following costs in setting up their existing allergen management plans/programmes:

- update allergen management guidelines
- 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.

Currently, as far as FSANZ is aware, all packaged labelled products in Australia and New Zealand containing lupin or lupin products declare the use of lupin as an ingredient in the label. 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 bakery items), although not 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 an assumption of 100 per cent voluntary compliance is reasonable and that no business would need to incur compliance costs as a result of the proposed change. FSANZ is asking the questions below to confirm assumptions in relation to the cost to business.

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

Although, current voluntary compliance is very high, it is very important to adopt this precautionary approach for the future due to growing use of lupin and uncertainty of future voluntary compliance. Also, including lupin in the list of mandatory allergens is expected to improve awareness of lupin allergy and provide more confidence for allergic individuals that information provided is complete and correct. . As such it should reduce the number of adverse health conditions associated with consumption of lupin and lupin products and reduce search and avoidance costs.

Stakeholders views are sought on the merits of this approach and in particular on the following:

- Are you aware of any lupin products that would be non-compliant with the proposed changes to the Code?
- Do you expect to have any notification¹³, education¹⁴, permission¹⁵, purchasing¹⁶, record keeping¹⁷, enforcement¹⁸, publication and documentation¹⁹, procedural²⁰, delay²¹, labelling²² or any other costs associated with the proposed changes to the Food Standards Code?
- Would implementation of the Option 3 cost more than implementation of the Option 2? If yes, why?
- Whether some level of education would be required to inform consumers that lupin is an allergen under this option?
- How many or what percentage of allergic reactions to lupin could be avoided under Option 3?
- Any views in relation to unintended consequences in relation to Option 3.
- What search and avoidance costs are likely to be avoided as result of this option?

5.4 Comparison of options and conclusion

Following stakeholder consultation on the options identified in this RIS, a decision RIS will be developed that seeks to identify the option with the highest net benefit.

6 Consultation

Targeted consultation has been undertaken with relevant interested parties seeking to obtain information on the likely costs and benefits if lupin was to be regulated as a new food allergen that requires mandatory declaration.

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 declarations consistent with current allergens. 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.

¹³ **Notification** - businesses face costs when they have to report certain events to a regulatory authority, either before or after the event has taken place.

¹⁴ **Education** - businesses face costs when keeping up to date with regulatory requirements.

¹⁵ **Permission** - businesses face costs when applying for and maintaining permission to conduct an activity.

¹⁶ **Purchasing** - businesses face costs when having to purchase a service (advice) or a product (materials or equipment) to comply with a regulation.

¹⁷ **Record keeping** - businesses face costs to keep statutory documents up to date.

¹⁸ **Enforcement** - businesses face costs when cooperating with audits, inspections and regulatory enforcement activities.

¹⁹ **Publication and documentation** - businesses face costs when having to produce documents for third parties.

²⁰ **Procedural** - businesses face non-administrative costs imposed by some regulations.

²¹ **Delay** - businesses face costs when administrative delays result in expenses and loss of income.

²² **Labelling** - declaring the presence of lupin on labels or displaying or providing information to consumers about the presence of lupin where a label is not required.

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 is seeking further information and feedback from industry, consumers and other stakeholders through the call for submissions.

A communication strategy has been developed for this Proposal, which includes one six-week public consultation period. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified via email about the availability of reports from public comment.

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

Individuals and organisations making submissions on this Proposal will be notified at each stage of the assessment.

All submissions (unless an adequate reason is provided) will be published on the FSANZ website as soon as possible after the public consultation period has closed.

7 References

Allergen Bureau - Voluntary Incidental Trace Allergen Labelling (VITAL)

<http://allergenbureau.net/vital/vital-downloads/>

(sourced 27 January 2016)

ASCIA-Access Economics Report (2007)

http://www.allergy.org.au/images/stories/pospapers/2007_economic_impact_allergies_report_13nov.pdf

(accessed 24 Mar, 2016)

Anaphylaxis Australia - Survey of members on product labelling, history of reactions and severity (2003)

<http://www.allergyfacts.org.au/images/pdf/AAI%20Food%20Labelling%20Survey%202003.pdf>

(sourced 3 April 2013)

Australian Bureau of Statistic – Australian population clock

<http://www.abs.gov.au/ausstats/abs%40.nsf/94713ad445ff1425ca25682000192af2/1647509ef7e25faaca2568a900154b63?OpenDocument>

(sourced 27 January 2016)

Australian Food and Grocery Council – Food Industry Guide to Allergen Management and Labelling

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

(sourced 21 October 2015)

Australian Food and Grocery Council – Product Identification Form

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

(sourced 11 September 2015)

Department of Agriculture and Food (2014) Western Australian Lupin Industry

<https://www.agric.wa.gov.au/grains-research-development/western-australian-lupin-industry>

(sourced 5 February 2014)

EFSA (2014) Opinion of the Scientific Panel on Dietetic products, Nutrition and Allergies on a request from the Food Safety Authority Ireland related to the evaluation of allergenic foods and food ingredients for labelling purposes. The EFSA Journal 12(11):3894.

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3894.pdf

(sourced 4 December 2015)

Goggin DE., Cameron EC, Mir G, Stuckey MS, Smith W and Smith PMC (2008)
Proteomic analysis of lupin seed proteins to identify conglutin β as an allergen Lup an 1. J Agric Food Chem.; 56: 6370-6377.

J. Gayraud, M. Mairesse, J.F. Fontaine, A.Thillay, V. Leduc, F. Rancé, L. Parisot, D.A. Moneret-Vautrin - The prevalence of sensitization to lupin flour in France and Belgium: a prospective study in 5,366 patients, by the Allergy Vigilance Network Department of Internal Medicine, Clinical Immunology and Allergology. - University Hospital, Nancy Cedex - France and Research Team 3999: Allergic diseases: diagnosis and therapeutics. Laboratory of Molecular Medecine and Therapeutics, Vandoeuvre Les Nancy, Vol 41, N1 1 22, 2009.

Lawrence F. Feick, Robert O. Herrmann, and Rex H. Warland (1983) ,"Search For Nutrition Information: Synthesis and Empirical Test", in NA - Advances in Consumer Research Volume 10, eds. Richard P. Bagozzi and Alice M. Tybout, Ann Arbor, MI : Association for Consumer Research, Pages: 624-629.

Loblay R, Soutter V, Swain A, Pinto E, Mullins RJ. (2006) "Prevalence of food allergy in childcare in central Sydney (CSAHS) and the Australian Capital Territory (ACT)". Internal Med J 36 (Suppl 6):A209

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Sipsas S (2008) Government of Western Australia, Department of Agriculture and Food, Australian Sweet Lupin – A very healthy asset. Government Publishing
Statistics New Zealand – New Zealand population clock
http://www.stats.govt.nz/tools_and_services/population_clock.aspx
(sourced 27 January 2016)

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

Zurzolo GA, Mathai ML, Koplin JJ, Allen KJ (2013) Precautionary allergen labelling following new labelling practice in Australia. J Paediatrics and Child Health 49:E306-E310