

16 June 2016
[15–16]

Call for submissions – Proposal P1026

Lupin as an Allergen

FSANZ has assessed a proposal prepared to assess the risk management options to regulate food containing lupin as an allergen and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 28 July 2016

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

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

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

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Supporting documents

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

<http://www.foodstandards.govt.nz/code/proposals/Pages/proposalp1026lupinas5830.aspx>

SD1 Risk Assessment
SD2 Consultation Regulation Impact Statement

Executive summary

Some foods can cause allergic reactions in susceptible individuals. As our choice of food options expands due to new foods and ingredients entering the food supply, there is an increased likelihood that new food allergens will emerge.

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, *Review of Regulatory Management of Food Allergens* (FSANZ, 2010). In relation to lupin, the report recommended FSANZ should develop a proposal to assess whether lupin and lupin-derived products should be included in the list of allergens requiring mandatory declaration in the *Australia New Zealand Food Standards Code* (the Code).

Lupin is a legume and is related to other legumes, peanut and soy, which have allergenic properties for some consumers. Lupin likewise has the potential to be an allergen, though in Australia and New Zealand, it is currently not as well-known or as prevalent an allergen as peanut or soy. This lower prevalence may be 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.

The first reports of lupin food allergy cases in Australia appeared in the scientific literature in 2004. At that time, a register of lupin-induced allergic food responses was introduced. Fourteen cases of lupin food allergy were recorded whilst the register was active; in addition there have been reports of at least another ten individuals in Australia being allergic to ingested lupin.

The use of lupin-derived ingredients (such as flour, grits and bran) has increased in food products produced in Australia over the last few years, 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 baked goods such as bread, muffins and cakes and pasta products. Information received by FSANZ indicates lupin-containing food products for human consumption are not widely available in New Zealand. The lower potential exposure to lupin from food in New Zealand compared with Australia is considered by FSANZ to be a major factor in the lack of reported lupin allergy cases in New Zealand. However, this may change over time as lupin products gain popularity in Australia and information on the potential health benefits spreads. The lupin market is more highly developed in other parts of the world, in particular various countries in Europe, where lupin has a long history in food products.

In order to manage the risk of allergy from consumption of lupin or lupin-derived products, FSANZ has prepared a draft variation to the Code which will require lupin to be declared whenever present in a food in the form of: an ingredient, an ingredient of a compound ingredient, a food additive or processing aid (including when used as an ingredient or component of these). FSANZ is also proposing a consequential amendment which will require oil derived from lupin to be named "lupin oil", rather than use the generic term "vegetable oil".

1 Introduction

Some foods can cause allergic reactions in susceptible individuals. The most well-known food allergens (also known as “major” food allergens) include wheat, egg, milk, peanuts, tree nuts, fish, crustacea, sesame seeds and soybeans. As food options expand due to new foods and ingredients entering the food supply, the likelihood of new food allergens emerging increases.

Lupin is a legume and is related to peanut and soy, which have allergenic properties for some consumers. Lupin likewise has the potential to be an allergen, though in Australia and New Zealand lupin allergy is currently not as well-known or as prevalent as peanut or soy. This lower prevalence may be at least partly due to the current lower use of lupin-derived ingredients and consequential lower exposure, 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.

The first cases of lupin food allergy in Australia were reported in the scientific literature in 2004 (Smith et al 2004). At the time of these reports Smith commenced a register of lupin-induced allergic food responses. The register (which is no longer active) recorded 14 cases of lupin allergy – 10 cases in South Australia and four cases in the Australian Capital Territory. In addition to these 14 cases, there have also been reports of at least ten individuals in Western Australia being allergic to ingested lupin.

The use of lupin-derived ingredients (such as flour, grits and bran) has increased in food products produced in Australia, and the lupin industry sees strong potential in developing uses of various lupin products in food. Lupin flour and bran are used in a variety of products such as pasta and bread and other baked goods such as muffins, cakes and biscuits. Currently lupin-containing food products for human consumption are not widely available in New Zealand, nor is there a lupin primary industry in New Zealand directed at human food production. However, this may change over time as lupin products become more popular in Australia.

Historically, most of the Australian sweet lupin (*Lupinus angustifolius*) crop was used for animal feed or exported to overseas markets. As a result of the increased interest in using lupin-derived products as a human food source 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.

1.1 The Proposal

FSANZ has prepared this Proposal to:

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

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

food additive or processing aid (including when used as an ingredient or component of these) is also included as part of the consideration of the Proposal.

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

1.2 The current standards

1.2.1 Lupin and natural contaminants

The only permissions in the Code which are specific to lupin and lupin products are in Schedule 19 – Maximum levels of contaminants and natural toxins.

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

Neither of these requirements is affected by FSANZ’s proposed requirement for mandatory declaration of lupin and lupin-derived products in food.

1.2.2 Lupin and mandatory declaration of food allergens

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

The following foods are allergens and currently listed in section 1.2.3—4 as requiring declaration (with some exceptions)¹:

- wheat
- crustacea
- egg
- fish
- milk
- peanuts
- soybeans
- tree nuts
- sesame seeds

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

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

¹ There are other foods and substances listed in Standard 1.2.3 that also require declaration but as these are not allergens they are not listed here

1.2.3 Ingredient labelling for lupin

The use of lupin as an ingredient in food is subject to the existing ingredient labelling requirements in Standard 1.2.4 – Information requirements – statement of ingredients. This Standard requires most packaged foods to declare each ingredient in a statement of ingredients using the common name of the ingredient, or a name that describes the true nature of the ingredient, or a generic name (listed in Schedule 10). However, foods that are not required to bear a label (e.g. unpackaged foods or foods that are made and packaged on the premises or is supplied in a restaurant or catering establishment) are not required to provide a statement of ingredients.

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

1.2.4 Regulation of lupin in food in other countries

1.2.4.1 Europe

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

Directive 2000/13/EC has since been repealed by Regulation (EU) No 1169/2011⁴. Annex II of Regulation (EU) No 1169/2011 is a list of substances or products causing allergies or intolerances, which includes lupin and products thereof. Paragraph (24) and Article 9(1)(c) of the EU regulation require information on any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II used in the manufacture or preparation of a food and still present in the finished product, even in an altered form, to be available to the consumer.

1.2.3.2 Other countries

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

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

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:368:0110:0111:EN:PDF>

³ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:109:0029:0042:EN:PDF>

⁴ Regulation (EU) No 1169/2011 of the European Parliament and the Council of 25 October 2011 on the provision of food information to consumers <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=EN>. Accessed 3 March 2016.

The United States Food and Drug Administration (USFDA) acknowledges⁵ that some people, including those allergic to peanuts, may have allergic reactions after eating lupin or foods containing ingredients from lupin. However, the *Food and Allergen Labeling and Consumer Protection Act* currently requires special allergen labelling for lupin or lupin-derived ingredients, as they are not classed as “major” food allergens⁶.

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

1.3 Reasons for preparing the Proposal

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

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

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

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ’s risk assessment for lupin and lupin-derived products as a potential food allergen is at SD1. A summary of the risk assessment findings from SD1, prevalence data contained in the COAG⁷ Consultation Regulation Impact Statement (SD2) and risks arising from the

⁵<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm410111.htm>. Accessed 3 March 2016.

⁶<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064880.htm>. Accessed 3 March 2016.

⁷ Council of Australian Governments

current regulatory regime are provided below.

In Europe, lupin allergy is well documented in the medical literature including case reports of severe allergic reactions to lupin in a range of food products, and clinical studies using double blind placebo-controlled food challenges (DBPCFC). Lupin has been recognised as a significant allergen in the European Union food regulations since 2007. In other jurisdictions e.g. USA, it is recognised as a food allergen but not categorised as “significant/major”.

Cases of lupin allergy in Australia were first reported in the medical literature in 2004 (Smith, 2004). Severe allergic reactions, including anaphylaxis, to lupin and lupin-containing food products have been reported from South Australia, Western Australia and the Australian Capital Territory. A Lupin Anaphylaxis Register set-up by Dr W Smith at the Royal Adelaide Hospital in 2004 contains 14 well-documented cases of lupin-induced anaphylaxis in Australia (this register is no longer updated). In addition to these 14 cases, there have also been reports of at least ten individuals in Western Australia being allergic to ingested lupin (Goggin et al, 2008). FSANZ is not aware of any clinically confirmed incidences of lupin allergy in New Zealand.

Australia and New Zealand have among the highest prevalence of allergic disorders in the developed world. The true prevalence of various food allergies in the population is uncertain. However, prevalence estimates reported in the medical literature for peanut allergy range between 0.7–1.4% 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% (the mid-point 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 who are peanut allergic and therefore may cross-react to lupin. This estimate does not take into account other individuals who are allergic to lupin-specific proteins 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, for example soy.

The rate of lupin sensitisation will be higher than that of lupin allergy, as sensitisation precedes allergy. As a result of the potential progression from sensitisation and to allergy, sensitisation can be used as a risk marker for allergy (although not all sensitised individuals will progress to an allergic state).

The international criteria (original criteria WHO 2000, and revised criteria Björkstén et al., 2008 and van Bilsen et al., 2011) for evaluating whether a substance is a food allergen of public health significance use a weight-of-evidence type-approach, taking account of:

- the 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.

These criteria have been used to evaluate the significance of lupin allergy in Australia and New Zealand (see SD1 for further information). The outcome of this assessment is that in Australia, lupin and lupin products represent a significant new allergen that presents a risk to allergic consumers.

Although the presence of lupin in food is currently limited, in both Australia and New Zealand,

it is likely to increase in the next few years. As a consequence, there will be higher dietary exposure to lupin in Australasia, which could result in a greater number of susceptible individuals exhibiting allergy to lupin.

In summary: The FSANZ lupin risk assessment concluded that lupin satisfied the criteria to be classed as a significant new food allergen and in Australia should be classed as an emerging food allergen of public health significance. Due to the expected increase in the use of lupin in food in the near future in Australia, which in turn leads to a potential increase in risk, it was also concluded an assessment of risk management options was needed. For New Zealand, based on the current low use and/or market for lupin in food and the consequential lack of, or very low, dietary exposure, lupin in food was not concluded to be of public health significance at the time of the FSANZ risk assessment.

FSANZ also has access to external allergy clinicians through the FSANZ Food Allergy and Intolerance Scientific Advisory Group (FAISAG) who are called on to provide expert advice on relevant allergy matters as needed. The conclusions of the FSANZ lupin risk assessment were supported by the FAISAG.

2.1.1 Current regulatory requirements and residual risk

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 on the label. When 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), FSANZ is aware of situations where the use of lupin as an ingredient is still declared to consumers. However, as this is voluntary, there may also be cases, including in the case of imported food, where lupin is used but not declared.

As lupin is not currently listed in section 1.2.3—4 as a food allergen requiring mandatory declaration (see section 1.2.2 above), the growing use of lupin and lupin products in food together with new and alternative uses, means that there is a risk that the presence of lupin in packaged food may not be declared to consumers. This could lead to an increased risk for susceptible individuals, since some packaged foods would declare lupin on the label and others may not.

Further examples of potential uses of lupin in food products in Australia and New Zealand which could lead to instances where the presence of lupin is not declared on the label of packaged food are listed below:

- The use of lupin as a processing aid. Processing aids are exempt from ingredient labelling (section 1.2.4—3)
- Food additives derived from lupin, such as lecithin. The food additive name or number (e.g. 'lecithin' or '322') would be required to be declared 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).

2.2 Risk management

Taking into account the risk assessment conclusions, the focus of FSANZ's risk management measures should be on managing the risk of allergic reactions occurring in susceptible individuals through potential consumption of food containing lupin or lupin-derived products.

Risk management measures are required for foods containing lupin and any substance derived from lupin because consumption of lupin-containing products may result in severe adverse health effects. Furthermore, the allergenicity risk of lupin can remain after processing.

2.2.1 Options

In order to manage the risk of consumption of lupin and lupin products, FSANZ considered the following non-regulatory and regulatory options during its assessment under section 59 of the FSANZ Act:

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.

Option 2: Develop a Code of Practice for food manufacturing industries.

Option 3: 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.

As explained below, FSANZ's assessment based on the information currently available was that option 3 would be most efficacious for managing the public health and safety risk. Notwithstanding this assessment and the preparation of a draft variation, stakeholders are encouraged to address the questions posed below in relation to each option. Responses will help inform FSANZ's decision on whether to approve, vary or reject the draft variation.

2.2.2 Impact analysis

2.2.2.1 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 a severe anaphylaxis reaction (and could result in death), to undeclared presence of lupin. Alternatively they may continue to incur significant search⁸ and avoidance costs as they attempt to ensure their food is allergen free.

FSANZ invites submissions from stakeholders on whether they see any merit in this risk management option. Information and advice on the costs of this option for government, industry and the community is also sought - see section 5.1, SD2.

2.2.2.2 Option 2 – Prepare a Code of Practice

A Code of Practice developed jointly by FSANZ and the 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

⁸ 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

relevant parties to comply with any recommendations.

The Food Industry Guide to Allergen Management and Labelling⁹ prepared by the Australian Food and Grocery Council (AFGC) provides guidance for industry in managing and labelling food allergens and could be used as a basis for a Code of Practice.

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 Code.

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 risk of this approach is that its voluntary nature might mean that some food manufacturers may not participate, leading to confusion and higher level of risk for consumers since some foods would be labelled while others would not. Bakeries and other suppliers of unpackaged foods are not necessarily covered by or familiar with the AFGC guide – which mainly applies to packaged food. Similarly food importers may not know about or follow the AFGC guide.

Stakeholder views are sought on the merit of this approach - see section 5.2, SD2.

2.2.2.3 Option 3 – Prepare a draft variation

This option involves the 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 in food as an ingredient (or an ingredient of 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), 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 individuals at risk are better able to avoid lupin and therefore avoid adverse health conditions associated with its 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.

FSANZ is not aware of any packaged or unpackaged lupin food product that does not declare the use of lupin. Therefore lupin products appear to be already consistent with the proposed change to the Code as the Code does not specify where and how the mandatory food allergens must be declared on the label. This means there will most likely be no regulatory cost for any food manufacturers presently using lupin.

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.

⁹ http://allergenbureau.net/wp-content/uploads/2013/11/Allergen_Guide_2007.pdf. Accessed 3 March 2016

Many Australian and New Zealand food manufacturing companies already require their ingredient suppliers to complete a Product Information Form (PIF) for each ingredient or substance added to food so companies can make risk management decisions to meet their regulatory obligations relating to the Code requirements, which include mandatory allergen declarations.

Including lupin in the list of mandatory allergens is expected to improve awareness of lupin allergy and provide information for allergic individuals who currently may not be able to verify whether lupin is present in foods. As such it should reduce the number of adverse health conditions associated with consuming lupin and lupin products and reduce search and avoidance costs.

Stakeholder views are sought on the merits of this approach. Information and advice on the costs of this option for government, industry and the community is also sought - see section 5.3 of SD2.

2.2.2.4 Proposed risk management option

The FSANZ assessment concludes that based on the information currently available, Option 3, a regulatory approach (amending the Code to require mandatory allergen declarations for lupin and lupin products), is likely to have the greatest net benefit and is therefore the current preferred option.

Other measures are unlikely to be as effective in managing the risk to public health and safety from consuming lupin and lupin products because they rely on voluntary actions, which may not be applied uniformly. For susceptible individuals, consuming lupin containing food represents a significant potential harm (possible death). Taking account of the potential severity of this risk and the potential growth in lupin containing food, a voluntary action is not a commensurate risk management measure.

The determination that the regulatory option is likely to have the greatest net benefit is based on qualitative analysis due to difficulty obtaining quantitative information from industry. Based on the current information FSANZ has to date, the potential costs of the proposed measure will not exceed the value of the anticipated direct and indirect benefits to the public. The consultation Regulation Impact Statement (RIS) in SD2 provides more details on the cost/benefit of each option.

In summary, FSANZ prepared variations to section 1.2.3—4 to apply mandatory allergen declaration requirements and to section S10—2 to specify the source name of lupin oil for generic name ingredient labelling conditions, because:

- it lowers the risk of future allergic reactions or developing allergic reactions, in susceptible people, from potentially consuming lupin and lupin products and supports the primary objective of protecting public health and safety
- adding an additional allergen to the existing allergen management framework would be expected to only impose a marginal cost, associated with updating the existing framework. The implementation cost of Option 3 would not be expected to be any higher than the costs involved with implementation of an industry Code of Practice.
- Option 3 would provide more certainty for those consumers wishing to avoid foods containing lupin.

The proposed variation also provides for a 12-month transitional period. FSANZ considers this appropriate as it balances the risk of a serious health outcome versus the resources

needed by industry to comply with the requirement. The current use of lupins in food in Australia and New Zealand is minor; information available to FSANZ suggests affected products already indicate the presence of lupin (either as a consequence of current Code labelling requirements or voluntary labelling). FSANZ is therefore proposing to vary section 1.2.3—4 so that mandatory allergen declaration requirements apply to lupin and lupin products.

The proposed mandatory requirements will require lupin to be declared when it is present in both packaged and unpackaged food as:

- an ingredient or as an ingredient of a compound ingredient
- a processing aid or as ingredient or component of a processing aid
- a food additive or as an ingredient or component of a food additive.

The proposed change to section S10—2 will require the specific source name of lupin oil to be declared for the generic name ingredient labelling conditions.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 59

2.4.1.1 Cost benefit analysis

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

A consultation RIS accompanies this call for submissions and assessment summary (SD2). It provides a qualitative cost benefit analysis using the information that was available to FSANZ for its assessment and its decision to prepare the draft variation. Additional information from this call for submissions may enable FSANZ to undertake a more quantitative-based impact analysis of the options for the Decision RIS. This depends, however, on the quality of data/information received from affected parties. The information/data received may result in FSANZ arriving at a different outcome.

The consultation RIS for this Proposal was approved by the Office of Best Practice Regulation (OBPR) in May 2016.

For further information and specific questions on which FSANZ is seeking comment, refer to section 5, SD2.

2.4.1.2 Other measures

For reasons described in section 2.2.3 of this document, FSANZ's assessment based on the information currently available is that no other measures would be more cost-effective than the proposed draft variation.

2.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards. The proposed draft variation will amend

Standards that apply in both Australia and New Zealand.

2.4.1.4 Any other relevant matters

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

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

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

Protection of public health and safety is FSANZ's most important objective in standards development.

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

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

The mandatory declaration requirements would ensure that consumers have access to information about the presence of lupin in both packaged and unpackaged foods. People who are allergic to lupin will therefore be able to identify more reliably the presence of lupin in a food and could make a choice to avoid the food product. In addition, for those people who are allergic to other legumes, e.g. peanut and soy, and are aware of the potential for cross-reactivity with lupin, the declaration of lupin will help them to make informed choices.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has assessed and characterised the risk of allergy from consumption of lupin in food, (see SD1 and 2). The risk assessments were based on the best scientific evidence available to FSANZ. They considered all available information (national and international), including

prevalence and cross-reactivity with other known food allergens.

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

The proposed variation to require mandatory declaration of the presence of lupin in food is consistent with EU legislation. Similar legislation for lupin as a food allergen does not currently exist in other jurisdictions, however many countries do have required mandatory labelling for the presence of the eight main food allergens, which is consistent with the Code. The lack of requirement for labelling of lupin as a food allergen in a particular country is likely to be due to a variety of reasons, which may include, the prevalence of food containing lupin in the country, the genetic disposition of the population and the country's approach to food risk.

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

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

Progression of this Proposal will create a 'level playing field' between Australasia and Europe as Europe already requires the declaration of lupin in food, due to its allergenicity potential. Progression of this Proposal will be inconsistent with other Australia and New Zealand trading partners and will be an additional burden on them if they import lupin containing food into Australia or New Zealand. However this is justified on the grounds of public health and safety and the expectation that the major source of lupin containing foods would be from the highly developed production of lupin in Europe, rather than other parts of the world.

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

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

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are no relevant policy guidelines for this Proposal.

2.5 Risk communication

2.5.1 Consultation

Targeted stakeholder consultation has already been undertaken to obtain information on the likely costs and benefits if lupin is 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 declaration requirements consistent with current allergens. Identified businesses were approached via email.

FSANZ was also able to link into a survey that the AFGC conducted on their PIFs. The AFGC PIF survey included some questions about lupin and FSANZ was able to follow up

with companies who provided relevant responses. FSANZ received 10 responses.

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

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on draft variations to the Code. In particular FSANZ is seeking further information and feedback from industry, consumers and other stakeholders on the proposed regulatory measure for managing the allergen risks associated with lupin in food, including the impacts and costs outlined in the impact analysis in the consultation RIS at SD2. Comments are specifically requested from the lupin industry and allergy susceptible individuals or organisations/groups representing such individuals. Additional information in response to this call for submissions may enable FSANZ to conduct a more quantitative analysis for the Decision RIS, depending on the quality of data/information received from affected parties. This could potentially result in FSANZ arriving at a different preferred option.

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

A communication strategy has been developed for this Proposal, 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. 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.

2.5.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

With the exception of regulatory requirements in the European Union, there are no relevant international standards and amending the Code to require mandatory declaration of food containing lupin and lupin products as food allergens may have a significant effect on international trade due to new labelling requirements. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement has been made to enable other WTO members to comment on the proposed amendments.

3 Draft variation

The draft variation to the Code and related draft explanatory statement are at Attachment A.

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

3.1 Transitional arrangements

The draft variations to sections 1.2.3—4 and S10—2, if approved, will commence on the date of gazettal and will have a 12-month transitional period from commencement of the variation. On expiration of the transitional period all products affected by this variation, including stock-in-trade items, must comply with the variation. FSANZ considers a 12-month transitional period is an appropriate time period which balances the risk of a serious health outcome versus the resources needed by industry to comply with the requirement and taking account of labelling costs. The current use of lupins in food in Australia and New Zealand is minor, with, at least some, products already indicating the presence of lupin (either as a consequence of current Code labelling requirements or voluntary labelling).

4 References

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FSANZ (2010), Review of the Regulatory Management of Food Allergens. <http://www.foodstandards.govt.nz/consumer/foodallergies/review/Documents/Review%20of%20the%20Regulatory%20Management%20of%20Food%20Allergens-FSANZ%20Dec%202010.doc>. Accessed 3rd March 2016.

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

Attachments

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

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



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

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

Dated [To be completed by Standards Management Officer]

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

Note:

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

1 Name

This instrument is the Food Standards (Proposal P1026 – Lupin as an Allergen) Variation.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 1.2.3 is varied by

[1.1] inserting after section 1.2.3—1

1.2.3—1A Transitional arrangements for prescribed variations

(1) For the purposes of this clause:

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

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

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

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

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

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

but not a combination of both.

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

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

substituting

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

[2] Schedule 10 is varied by

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

[2.2] inserting after section S10—1

S10—1A Transitional arrangements for prescribed variations

(1) For the purposes of this section –

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

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

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

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

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

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

(b) the Code as amended by the prescribed variation;
but not a combination of both.

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

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

substituting

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

Attachment B – Draft Explanatory Statement

1. Authority

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

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

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

2. Purpose

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

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

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1026 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

5. Statement of compatibility with human rights

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

6. Variation

Item 1 amends Standard 1.2.3.

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

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

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

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

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

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

Item 2 amends Schedule 10.

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

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

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

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

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