

**Submission to
Food Standards Australia New Zealand
In relation to
Proposal P1026 - Lupin as an Allergen**

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The Allergen Bureau Ltd

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The Allergen Bureau Ltd

The Allergen Bureau Ltd was established in 2005, and currently operates on a membership basis. The Allergen Bureau exists to share information and experience within the food industry on the management of food allergens to ensure manufacturers and consumers receive relevant, consistent and easy to understand information on food allergens.

The Allergen Bureau provides rapid responses to questions concerning the management of food allergen risks in food ingredients and manufactured foods in Australia and New Zealand - and more recently to a global food industry audience.

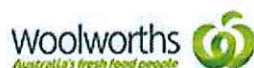
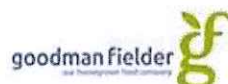
The growth in the incidence of food allergens is an international phenomenon. The Allergen Bureau draws on and disseminates information from all over the world on food regulations and the latest scientific research on food allergens including emerging food allergens.

Most of the visitors to the Allergen Bureau website are from Oceania and Europe. About 46% of website visitors are from Oceania (Australia is 38% and New Zealand is 7% of total visitors) and 32% are from Europe (UK 7%; Germany; 6%; France 4%, The Netherlands 3% of total visitors). The Americas make up 10% of visitors (USA 7% and Canada 2% of total visitors); Asia another 10% (India 2% of total visitors); and Africa under 2% (South Africa 1% of total website visitors). These visitors include representatives from food industries in these countries as well as research groups and consumers.

The Allergen Bureau is a wonderful example of cooperation amongst competitors in the food industry, with national and multi-national food manufacturing and marketing companies, suppliers, importers, exporters, retailers and consumer groups cooperating and sharing information on managing the risks of food allergens in industry in the interests of consumers.



Allergen Bureau Full Members:





Allergen Bureau Associate Members (Category A, B & C):

- Advancing Food Safety – SAI Global
- All Systems Go
- Arrow Scientific Pty Ltd
- Ballantyne
- Bellamy's Organic
- Chadderton Food Safety Pty Ltd
- Diseb Food Group
- Food Laboratories (Aust) Pty Ltd
- Flavour Makers
- Genoa Foods
- Hamilton Grant
- KADAC
- Orange & Green
- Sci Qual International
- Stahmann Farms Enterprises
- Susan Day Cakes
- The Gourmet Guardian
- Vatmi Industries
- Vitasoy



Submission by the Allergen Bureau in relation to the Food Standards Australia New Zealand Proposal P1026 - Lupin as an Allergen

The Allergen Bureau welcomes the opportunity to make this submission with regard to the Proposal P1026 - Lupin as an Allergen.

Lupin is an established allergenic food that is required to be declared on food labels in the European Union. The increased use of lupin and lupin fractions as food ingredients in Australia and the potential increase in their presence in foods in both Australia and New Zealand make the FSANZ consideration of this matter locally both timely and appropriate.

The Allergen Bureau VITAL® Program

The primary objective of the Allergen Bureau and the Voluntary Incidental Trace Allergen Labelling (VITAL®) Program is to ensure manufactured food is safe to consume for the vast majority of food allergic consumers. The VITAL Program can be used to assist food producers in presenting allergen labelling accurately and consistently for people with food allergy and by providing consistent food labels that declare the presence of allergens that are present due to documented, unavoidable and sporadic cross contact, thus enabling allergic consumers and their carers to avoid purchasing foods that may present a personal risk.

Comments on the Proposal

Lupin as an Allergen

The Allergen Bureau considers that the Risk Assessment in Supporting Document 1 provides an excellent summary of the prevalence and the public health & safety risks associated with lupin allergy in both Europe and in Australia and New Zealand. However, the assessment is limited to lupin based foods and ingredients containing lupin protein. The Allergen Bureau suggests that document could be improved by the inclusion of an assessment of the risk posed by fully refined (i.e. N/RBD - degummed, neutralised, bleached and deodorised) lupin products that do not contain appreciable levels of protein.

In respect to the relative risks presented by lupin protein compared to other legumes, the Allergen Bureau's VITAL Scientific Expert Panel (VSEP) (see Appendix for VSEP members) reviewed data from Double Blind Placebo Controlled Food Challenge (DBPCFC) studies for lupins, soy and peanuts (Taylor et al 2014). As described in Supporting Document 1, the VSEP harvested data from accessible published and unpublished sources and used interval censoring survival methodology to establish population dose distribution models from which eliciting doses (ED_n - the dose eliciting a

response in n% of the allergic population) could be determined. For peanut there were sufficient challenge study results to enable the determination of the ED01 whereas for soy and lupin the data were only sufficient to enable determination of the 95th percentile lower confidence interval of the ED05 (ED05 95% lcl). When comparing these values, it should be noted that for allergens for which both ED values were determined, in general the ED05 95% lcl was marginally higher than the ED01, and thus the latter represents a more conservative marker of risk. The VSEP recommended the following reference doses for use in VITAL:

Allergen	Reference Dose (mg protein)	Basis
Peanut	0.2	ED01
Soy flour / infant formula	1.0	ED05 95% lcl
Lupin	4.0	ED05 95% lcl

As a significant food allergen in the EU and an emerging allergen in Australia and (potentially) New Zealand), the Allergen Bureau supports the inclusion of lupin in the list of foods in Standard 12.3-4 that are required to be declared when present as a result of addition to food. However, we also note the outcome of the recently completed Proposal P1031 Allergen Labelling Exemptions in which fully refined soybean oils and soybean oil distillates in the form of tocopherols and phytosterols were excluded from allergen declaration on the basis that they contained less than <1 mg/kg soy protein. The VSEP analysis discussed above suggests that there is a hierarchy in terms of relative potency of the 3 legume allergens, with the eliciting dose for lupin protein being approximately 4 times that for soy protein. On this basis, the Allergen Bureau suggests that it would be consistent with the risk assessment process used on P1031 to consider similar labelling exemptions to applicable highly refined lupin products that do not contain appreciable levels of protein.

Labelling

As indicated in the Call for Submissions, a majority of lupin products, such as lupin flour, lupin meal and lupin protein fractions are already identified on food labels by an appropriate name or description that includes "lupin". Consequently, the immediate impact of meeting the minimum requirement for mandatory labelling of the presence of added lupin may be expected to be minimal.

It should also be recognised that many food manufacturers voluntarily comply with the AFCG best practice allergen labelling guidelines, which require declaration of the mandatory allergens both in the ingredient list (preferably bolded) and also in the summary "Contains:" statement following the ingredient list. The inclusion of lupin in the list of mandatory allergens in Standard 1.2.3-4 will



mean that those manufacturers who follow the AFGC best practice guidelines will have to revise the format of their ingredient listings to bold the word “lupin” in the ingredient name and also add “lupin” to the “Contains:” statement in order to maintain consistent allergen labelling across their product ranges and to avoid potential consumer confusion.

Where lupin may constitute a cross contact risk, a change to the precautionary statement may be required.

Precautionary Allergen Labelling

In addition to food allergens present in a food due to intentional inclusion as part of a recipe, they may also be present due to unintentional cross-contact. This can occur at any point in the supply chain due to the type of ingredients used or through the use of shared equipment and processes during manufacture. Even under conditions of Good Manufacturing Practice (GMP) cross-contact may be difficult to eliminate entirely, leading manufacturers to use precautionary advisory statements to advise allergic consumers.

The Allergen Bureau’s VITAL® Program is a standardised allergen risk assessment process for food industry. The VITAL Program was developed to make a single simple standardised precautionary statement available to assist food producers in presenting allergen advice consistently for allergic consumers and specifies a particular precautionary allergen statement to be used according to the level of cross contact identified.

The VITAL Program allows the case-by-case assessment of likely sources of allergen cross contact from raw materials and the processing environment, plus an evaluation of the amount present and a review of the ability to reduce the allergenic material from all contributing sources. It also provides for ongoing monitoring and verification of the risk assessment process to ensure any changes to the level of risk are acted upon without delay.

Although, lupin is not currently in the list of allergens subject to mandatory declaration in Australia and New Zealand, it is already included in the VITAL Program Version 2.0 to assist food manufacturers that export to the European Union and, consequently will be available for local manufacturer from the commencement of an amended labelling requirement.

Through the use of shared harvesting, transport and storage facilities, there is a significant potential for cross-contact between grain crops. In many cases, this may be economically unavoidable for producers and beyond the control of food processors. Whilst it is recognised that the presence of a listed allergen in a food under these circumstances does not meet the conditions

for mandatory labelling set out in Standard 1.2.3-4, periodic enquiries to the Allergen Bureau Helpline indicate that there is, nonetheless, a degree of confusion on this point amongst some manufacturers concerned that they are knowingly but unavoidably adding an allergen as a component in their products. The Allergen Bureau considers that this is a matter which should properly be addressed through a risk based voluntary cross-contact labelling process such as VITAL. The Allergen Bureau suggests that the current application provides FSANZ with an opportunity to include a clarification statement in its Approval Report indicating that co-mingling of grains during harvesting, transport or storage, does not trigger a mandatory labelling requirement under Standard 1.2.3-4 but should be addressed through the application of a science based risk assessment such as VITAL .

Analysis of Lupin Protein

In food production, three lupin species are commonly used: white lupin (*Lupinus albus*), blue/sweet lupin (*Lupinus angustifolius*) and yellow lupin (*Lupinus luteus*). The main type of lupin grown in Australia is *L. angustifolius* (predominantly WA) but *L. albus* is also grown in smaller amounts in various Australian grain growing regions. The variety of lupin species is important, as the antibodies in different ELISA kits may not be able to detect all species efficiently - which could lead to reduced sensitivity and or false negatives, depending on the source of the lupin. Overall, the analytical implications for lupin are probably no more significant than they are for other allergens, and can be effectively managed by informed laboratories and analysts working with the food producers. Work by the AOAC to develop a standardised reference method for allergens will be of value to regulators. However, the advent of such a method being developed in the next two years is low. In the meantime, the availability of an external proficiency program (e.g. <http://fapas.com/>) or an internal check sample program utilising local grains does provide a way to look at laboratory performance and the ability of a laboratory to reliably detect lupin.

Methods for detecting lupin in food

There are a number of commercially available ELISA assays for the detection of lupin, which each have advantages and disadvantages, mainly relating to their ability to sensitively detect different lupin species and cross-reactivity with other legumes. There are also several lupin lateral flow assays available for Clean-in-Place (CIP) samples and environmental monitoring.

Sensitivity:

In respect of the sensitivity of an assay- the preferred value is LOQ (limit of quantitation). In order to confirm cleaning validations and to check finished product for unexpected presence, the LOQ needs to be relatively sensitive.

The lupin ELISA assays available from the main kit manufacturers have reported LOQs ranging from

0.5ppm Lupin Flour Protein to 2.5ppm Lupin (since ~40% of lupin seed is protein, then units of Lupin need to be divided by approximately 2.5 to convert to an equivalent reporting unit of Lupin Protein). This provides a very similar level of detection sensitivity to that seen for other food allergen ELISA assays. However, caution needs to be exercised in regard to whether the reported LOQs are applicable to all sources of lupin. Kit manufacturer's may use antibodies targeted against all three common lupin species used in food production (*L. albus*, *L. angustifolius* and *L. luteus*) to help ensure applicability with local and imported foods that may have different sources of lupin. Other assays may not indicate which species of lupin is targeted and therefore the ability to detect all commonly encountered lupin species can be assessed from the Manufacturer's kit validation report and experimentally from samples with known sources of lupin.

Particularly where there is a potential for significant cross-contact between lupin and other related legumes, notably soy and chickpeas, the use of two lupin assays with different cross-reactivity profiles may be necessary to enable low level lupin detection in a sample and help rule out false positives.



Conclusion

The Allergen Bureau supports the objective of the proposal to include lupin in the list of allergenic foods in Standard 1.2.3-4 that are required to be declared when present as a result of addition to food. However, as reported by the Allergen Bureau's VITAL Scientific Expert Panel, there is a hierarchy in terms of relative potency of the primary legume allergens, with the eliciting dose for lupin protein being approximately 4 fold higher than soy and potentially 10 fold or higher than peanut protein. Consequently, the Allergen Bureau suggests that consideration be given to exemption of highly refined lupin products that do not contain appreciable levels of protein.

It is also suggested that the Approval Report recognise that manufacturers who apply the AFGC Best Practice Allergen Labelling Guidelines will have to change their labels to maintain consistency and avoid potential consumer confusion.

In relation to voluntary cross-contact labelling, lupin is already included in the Allergen Bureau's VITAL® Program Version 2.0, to assist businesses exporting to the EU, and no changes will be required to enable its use for the domestic market.

The use of at least three different species of lupin as food presents some challenges in respect of detection and analysis. However, overall, the analytical implications for lupin are probably no more significant than they are for other allergens and can be effectively managed by informed laboratories and analysts working with the food producers.

The Allergen Bureau also supports the Australian Food and Grocery Council submission on this proposal.

Tom Lewis
Allergen Bureau Chief Executive



Appendix. The Allergen Bureau's VITAL Scientific Expert Panel

The Allergen Bureau's VITAL Scientific Expert Panel (VSEP) consists of international scientists specialising in allergen management, food allergy and risk assessment.

The VSEP is a collaboration between the Allergen Bureau, Food Allergy Research & Resource Program (FARRP) of the University of Nebraska & the Netherlands Organisation for Applied Scientific Research (TNO).

Members of the Panel are:

- [REDACTED] (FARRP, Chair of Panel)
- [REDACTED] (FARRP)
- [REDACTED] (Unilever)
- [REDACTED] (TNO)
- [REDACTED] (Allergen Bureau consultant)
- [REDACTED] Paediatric Allergist, Australia)

Summary of VITAL Scientific Expert Panel Recommendations

<http://allergenbureau.net/wp-content/uploads/2013/11/VSEP-Summary-Report-Oct-2011.pdf>