

Comments from the Victorian Departments of Health and Human Services, Development and Economic Development, Jobs, Transport and Resources

Due date of submission: 28 July 2016

The Victorian Departments of Health & Human Services, and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to respond to the issues raised in the Consultation paper for Proposal P1026 – Lupin as an Allergen.

Proposal P1026 - Lupin as an Allergen proposes risk management options developed by Food Standards Australia New Zealand (FSANZ) to regulate food containing lupin as an allergen.

From the FSANZ assessment report it is understood that:

- Lupin causes sensitivity and in some cases, allergic reactions (including anaphylaxis) in individuals. Some individuals that are sensitive to lupin may also experience cross-reactivity and in some cases, allergic reactions, to foods currently identified as major allergens in the Australia New Zealand Food Standards Code (the Code).
- Under the Code, allergens are identified when listed as an ingredient on packaged food or, where a food is not required to bear a label, the declaration must be stated in labelling that is displayed in connection with the display of food, or provided to the purchaser on request.
- There are currently circumstances in which lupin may be present but not declared in the ingredients list, for example when:
 - lupin is used as a processing aid;
 - food additives derived from lupin are added, such as a lecithin; and
 - lupin is included as an ingredient of a compound ingredient and that compound ingredient made up 5% or less of the final food.

A consultation Regulation Impact Statement (RIS) has been prepared by FSANZ, proposing three options including: (i) maintain the status quo; (ii) prepare an industry code of practice; or (iii) prepare a draft variation to the Code.

The departments support Option 3, to prepare a draft variation to Section 4 of Standard 1.2.3 – Information requirements to require a mandatory allergen declaration on the label, or, where a label is not required, for businesses to provide access to information about the presence of lupin in food being sold. To accompany that change, the departments support the proposal to amend Schedule 10 – Generic names of ingredients and conditions for their use, to include lupin as the specific source name of the oil to be declared- appearing as ‘lupin oil’ rather than ‘vegetable oil’.

The identification of lupin as an allergen, in addition to the potential cross-reactivity of consumers with peanut and soy allergies supports the need to recognize lupin as an allergen in the Code. In Europe and the US, lupin and its products are recognised as allergens, and in Europe it has been mandatory to declare its presence since 2007.

The departments provide further consideration of the three options, and related questions posed by FSANZ, below.

Option 1 – Maintain the status quo:

- *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?*

Given the wide range of current and potential food applications of lupin, such as baked goods; vegetarian products; whipped products, fillings and glazes; ice cream, desserts, mayonnaise and dressings, high protein energy drinks, and lupin protein concentrates and isolates used as binding and emulsifying agents, the departments do not support Option 1 - maintaining the status quo.

It was noted in the proposal that the allergenicity of lupin was retained after extrusion cooking, boiling, autoclaving and microwave heating. Under the current provisions for labelling, consumers who are sensitive or allergic to lupin are likely to be at risk of unintentional lupin consumption, particularly given the expanding use of lupin and the range of foods in which lupin might be present, but not labelled as an allergen.

The departments recommend that FSANZ consider the expected rise in hospitalisations from anaphylaxis, and potential death of consumers who suffer an allergic reaction from consuming foods that do not declare the presence of lupin either as an ingredient in an unpackaged food, food additive or processing aid in retaining the status quo.

Other costs from maintaining the status quo include:

- Diagnosis of sensitivity, and in some cases, allergy, to lupin may become more difficult when an individual may not be aware of the ingredients of a food that caused the sensitivity or reaction.
- If an allergic reaction occurs, administration of medication is followed up with hospitalisation which can result in lost earnings to the individual, an increase in the cost of care for the healthcare system, lost productivity for employers, incurred opportunity costs for carers, and other cascading effects.
- Voluntary declaration is likely to lead to more individuals needing to purchase and carry EpiPens following diagnosis of a lupin allergy should lupin as an ingredient, food additive or processing aid be more widely adopted by the food industry. This product is subsidised through the Pharmaceutical Benefits Scheme at a cost to the Australian Government.

Option 2 - Prepare a Code of Practice:

- *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?*

Option 2 proposes an industry Code of Practice be prepared, and is not supported by the departments. The risk to consumers increases with this option due to the voluntary nature of the code, lack of enforcement for non-compliance, and the risk that consumer confidence rises in perceived labelling compliance, when in fact compliance may not warrant that confidence.

Given the seriousness of an allergic reaction to lupin, the departments do not support a voluntary approach to labelling of lupin. The departments note that the voluntary guide prepared by the Australian Food and Grocery Council '*The Food Industry Guide to Allergen Management and Labelling*' provides recommendations and guidance for the production and labelling of foods containing allergenic substances based on the requirements of the Code. Therefore, variations to those standards that address labelling of lupin in the Code can be expected to drive amendments to this Guide to facilitate implementation of new practices with adequate assurance that risks to

consumers are minimised.

Option 3 – Prepare a draft variation:

- *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 notification, education, permission, purchasing, record keeping, enforcement, publication and documentation, procedural, delay, labelling 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?*

The departments support option 3, preparing a draft variation to include lupin and lupin products in section 1.2.3–4 to require a mandatory allergen declaration; and to include lupin in Schedule 10 to provide for the specific source name of 'lupin' oil. It is important from a public health perspective that consumers can access information about the presence of lupin either in connection with the display of food, or provided to them on request.

Given the likely increased use of lupin in the food supply, and associated increased incidence of lupin allergy, education will be required to inform consumers as well as food businesses and manufacturers of changes to the allergens that must be declared. As noted in the proposal, adding an additional allergen to the existing allergen management framework is a minor change.

The departments note that FSANZ has consulted with Pulse Australia regarding receivable standards and suggests that lupin has the potential to also contaminate wheat. The current receivable standard focuses on the amount of wheat that is acceptable in lupin supply (as opposed to the latter). Contamination of lupin supply with wheat may require the identification of wheat/gluten as an allergen on the Product Information Form for lupin ingredients. The departments suggest that Pulse Australia/the industry should be encouraged to consider a receivables standard for lupin for human consumption.

Some of the benefits of Option 3 include, as noted in the proposal, reduced risk of unintentional consumption of lupin by allergic individuals due to lupin declaration on labels. Avoidance of foods that may contain lupin, or situations where it may occur – such as dining in cafes and restaurants – and the associated costs of this behaviour is likely to be reduced under Option 3. It is agreed that the evidence presented in the proposal addressing the cross-reactivity potential of lupin with other legumes that cause allergies in some people, such as peanut or soy, supports Option 3 being of benefit for this group also.

With the potential health benefits already claimed around the consumption of lupin, such as gluten free, low Glycemic Index rating, high in fibre, soluble fibre, protein, antioxidants and phyto-sterols and low in starch, the expansion into the human food stream in Australia through marketing of these attributes will likely increase exposure to a food that a portion of the population is sensitive to.

The proposed 12 month implementation period is shorter than other changes to the Code, such as Country of Origin labelling changes. Some manufactured products likely to contain lupin have a

shelf life in excess of 12 months, such as pasta, and may still exist in trade within that timeframe. Foods containing lupin as an ingredient, and listed as such, will be identifiable by consumers. However, regulatory bodies may encounter the situation following the 12 month implementation period where a consumer has suffered an allergic reaction to a food where lupin has been used as a processing aid or additive is present in a compound ingredient or vegetable oil, and the food does not comply mandatory allergen labelling. A food recall would be initiated in this case.

While the departments support lupin being a declared as allergen in the Code, we would appreciate some advice from FSANZ on how the presence of lupin can be tested for, for compliance purposes.

Risk management decisions taken by regulatory bodies with respect to undeclared allergens are often difficult to make. This is partly due to a lack of clear data of allergen threshold levels, and the capacity to identify low levels of allergens in packaged products. This situation arises because there is a lack of validated methods for identifying a specific allergen in a range of different food matrices. This becomes a problem particularly if threshold levels of allergens are set at low levels or are unknown as is the case for individuals who may be highly sensitive. Until validated methods have been developed for the full range of suspected allergens in different food matrices, risk management decisions by authorities or manufacturers will be difficult and potentially inconsistent. This will also be the case with lupin whilst testing for the presence of lupin proteins using the enzyme-linked immunosorbent assay (ELISA). Variations in interpretation of the results can therefore be expected to arise when determining if the risk of an allergic reaction could exist in foods containing lupin below the level of quantification.