Submission to

Food Standards Australia New Zealand

In relation to

Proposal P1031 Allergen Labelling Exemptions

23 September 2013

The Allergen Bureau Ltd

ACN 162 786 389

Contact for this Submission: [redacted]
info@allergenbureau.net

The Allergen Bureau Ltd

The Allergen Bureau Ltd was established in 2005 as an initiative of the Australian Food & Grocery Council Allergen Forum, and currently operates independently on a membership basis. The overall objective of the Allergen Bureau is 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.

Almost 20% of visitors to the Allergen Bureau website come from North America (Canada and USA) and over 10% from Europe with the majority from the UK. These visitors include representatives from food industries in these countries as well as research groups and consumers.

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. 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.

The Allergen Bureau is the product 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
- All Systems Go
- Arrow Scientific Pty Ltd
- Bellamy's Organic
- Chadderton Food Safety Pty Ltd
- Diseb Food Group
- Food Laboratories (Aust) Pty Ltd
- Hamilton Grant
- Ingredion
- KADAC
- Orange & Green
- Sci Qual International
- Vatmi Industries

Submission by the Allergen Bureau in respect of proposal P1031 – Allergen Labelling Exemptions

The Allergen Bureau welcomes the opportunity to make this submission to the Proposal P1031 Allergen Labelling Exemptions, a proposal that has been actively supported by the Allergen Bureau Allergen Labelling Exemptions working group.

In summary, the Allergen Bureau is supportive of the risk assessments and resulting risk management recommendations for three out of the four proposed products:

- Fully refined soybean oil;
- Tocopherols and phytosterols from soybean oil;
- Distilled alcohol from wheat or whey.

With respect to the fourth product:

- Glucose syrup from wheat starch

The Allergen Bureau has comments to contribute both in relation to the risk assessment and also for the recommended risk management approach as we believe this can be demonstrated to impose additional costs and compliance requirements for Australian and New Zealand companies, both manufacturers and importers, where there is not a demonstrable consumer food safety benefit.

This submission will describe how the Allergen Bureau working group has contributed to this proposal, and more generally towards clear and consistent allergen labelling to facilitate safe choice for allergic consumers. The question of the scientific basis for the recommended approach to exemptions and the reference to the work of the VITAL® Scientific Expert Panel (VSEP) has been included in the attachment to this Allergen Bureau submission, prepared by Dr Simon Brooke-Taylor (Allergen Bureau consulting scientist and a member of the VITAL Scientific Expert Panel (VSEP)) in consultation with other members of the VSEP and is a key part of this submission.

The Australian /New Zealand regulatory background

The Australia New Zealand Food Standards Code Standard 1.2.3 requires the mandatory labelling of the following allergen foods or products derived from them when present as a result of having been added as:

(a)an ingredient; or
(b)an ingredient of a compound ingredient; or
(c)a food additive or component of a food additive; or
(d)a processing aid or component of a processing aid:

- Cereals containing gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains except in beer and spirits
- Crustacea
- Egg
- Fish (including molluscs), except for isinglass derived from swim bladders and used as a clarifying agent in beer and wine.

- Milk
- Peanuts and soybeans,
- Tree nuts, except coconut,
- Sesame seeds.

Of particular relevance to this Proposal are the requirements to declare wheat and its products, soybean and soybean products and milk and milk products when the derived substances have undergone very significant processing and present negligible risk to allergic consumers.

The Allergen Bureau Objective

The primary objective of the Allergen Bureau and VITAL® is to ensure manufactured food is safe to consume for the vast majority of food allergic consumers 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.

To facilitate communicating accurately and consistently to the allergic consumer, the Allergen Bureau established a working group to work towards Allergen Labelling Exemptions.

The key points relevant to this work are:

- Some foods, derived from allergenic sources, are safe for people who are allergic to the original foods i.e. highly refined foods
- This approach has been established and used in EU with EFSA completing risk assessments and granting permanent labelling exemptions to a range of highly refined substance.
- FSANZ had established an approach for allergen labelling exemptions, with the first exemptions included in the Code being:
    - beer & wine are exempt from declaring cereals containing gluten and their products
    - beer & wine are also exempt from declaring fish where isinglass (which is derived from the swim bladder of fish) is used as a fining agent,.
- The working group volunteered to provide input into a proposal to amend the Code for certain highly refined foods on the permanent exemption list in EU to be exempt from allergen labelling in ANZ
- This will provide a wider food choice for consumers without increasing the risk of exposure to food allergens.

The Allergen Bureau Allergen Labelling Exemptions (AB ALE) working group met with key FSANZ staff to discuss potential ways of working for FSANZ and ANZ industry (in this case represented by the Allergen Bureau working group) to progress allergen labelling exemptions for highly refined substances.

In the FSANZ meeting we discussed our preference to work proactively in providing industry and technical information to support the FSANZ work being scoped to progress the recommendations coming out of the review. As can be seen from the information to date for the top three prioritised allergen exemptions, there has been significant investment by the Allergen Bureau working group and interested companies to assemble and develop the information. In particular, we discussed the costs and resource requirements for industry to develop application dossiers to the Application Handbook requirements and how, as an industry group we felt we could best support the recommendation to move forward with further allergen labelling exemptions by responding to a FSANZ Proposal, rather than having to develop application dossiers to meet very specific requirements and formats for each of these. This proposal for a way of working was supported in principle by the FSANZ members around the table.

To this end, the working group two key pieces of work were undertaken:

1. Determining local ANZ industry prioritisation for the allergen exemptions granted in other internationally regulated countries/regions; and
2. Determining the status and availability of information to support labelling exemptions for highly refined substances.

Based on the results of the Industry Prioritisation questionnaire, the top three industry prioritized allergen labelling exemptions were identified for the AB ALE WG to progress as a first stage with FSANZ. These were:
65.2% - Wheat & other cereals containing gluten (glucose syrups and maltodextrins)
57.7% - Soy (fully refined oil or fat)
49.3% - Soy (E306, natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate)

The working group co-ordinated with key industry stakeholders to provide FSANZ with a dossier of available material to feed into the proposal. This material included contributions from Australian and New Zealand companies (specifically Cargill for RBD Soybean oil, Danisco for Soy tocopherols and Manildra for Glucose Syrup from wheat), as well as contributions from international companies (Unilever) who were well linked in with the EU allergen labelling exemptions work.

In progressing this proposal, the Allergen Bureau ALE working group has been strongly supported by the range of industry organisations including:
Australian Food and Grocery Council
New Zealand Food and Grocery Council
Ai Group Confectionery Sector
Australian Oilseeds Federation
Food and Beverage Importers Association

P1031 Summary:

A summary of the risk assessment and recommendations for each of the four products considered in this proposal is provided below:

1. Fully refined soybean oil:

N/RBD is virtually devoid of any protein as a result of processing steps required to produce such oils.
Risk assessment conclusion is that N/RBD soybean oil presents negligible risk to soybean allergic consumers.
Ultimately an N/RBD soybean oil must be sufficiently clear, odourless and free of free fatty acids to be fit for purpose and by virtue of this process will contain minimal levels of protein. On this basis it is proposed for exemption from the requirement for allergen labelling.

2. Tocopherols and phytosterols from soybean oil:

Phytosterols and tocopherols are highly processed products derived from the soybean based deodoriser distillate. Analytical data confirmed that protein was not detected.
The risk assessment concludes that tocopherols and phytosterols derived from deodoriser distillate in the manufacturing of N/RBD soybean oil present negligible risk to soybean allergic consumers, and subsequently are proposed for exemption from the requirement for allergen declaration.

3. Distilled alcohol from wheat or whey:

There is general scientific agreement that, in properly controlled distillation process, non-volatile substances such as lactose and proteins from whey are not found in distillate. On this basis, distilled alcohol (and products made from distilled alcohol, such as vinegar) would not contain protein.

The risk assessment concludes that alcohol distilled from wheat or whey presents negligible risk to susceptible consumers and is proposed for exemption from the requirement for allergen labelling.

In conclusion, we are supportive of the risk assessments and the risk management recommendations for each of these three products as they have resulted in proposed exemptions that are evidence based and are internationally consistent (aligned to those already in place in European Union) and do not propose unique Australian/New Zealand compliance requirements or additional costs.

4. Glucose syrup from wheat starch:

The risk assessment concluded that based on the available evidence, consumption of wheat-derived glucose syrup that had been purified and prepared as described in the process (with a gluten content of 10-20mg/kg) is likely to present negligible risk to the majority of wheat allergic consumers.

However, to ensure that gluten levels in glucose syrup are as low as technically achievable, the proposal is for glucose syrup made from wheat starch be exempted from mandatory allergen labelling where the residual gluten content is less than or equal to 10mg/kg.
The Allergen Bureau Allergen Labelling Exemptions working group supports the proposed exemption for allergen labelling for Glucose Syrup from Wheat however we do not support the reasoning and recommendations for a residual gluten content to be less than or equal to 10mg/kg.

Allergen Bureau Allergen Labelling Exemptions working group response
Supporting Document 1
Risk Assessment - Proposal P1031
Allergen Labelling Exemptions

The FSANZ risk assessment concluded that based on the available evidence, consumption of wheat-derived glucose syrup that had been purified and prepared as described in Appendix 2 would present negligible risk to the majority of wheat allergic individuals; such syrups would also be suitable for those with Coeliac disease.

In the attachment to this Allergen Bureau submission, prepared by Dr Simon Brooke-Taylor (Allergen Bureau consulting scientist and a member of the VITAL Scientific Expert Panel (VSEP)) in consultation with other members of the VSEP, there is a detailed response addressing the Risk Assessment report, conclusions and Supporting Document 1 for Glucose syrup derived from wheat provided.

Dietary Exposure Assessment for Glucose Syrup from Wheat:

1. The dietary exposure assessment used in this report is based on a range of data including:

- arbitrary amounts proposed for consumption in one eating occasion;
- the amount of glucose syrup from wheat present in various confectionary (good examples provided in the Ai Group Confectionery Sector submission);
- the assumption that all glucose syrup used in the confectionery is from wheat;
- the assumption that all glucose syrup contains the maximum level of gluten proposed, when market data has demonstrated the actual levels are considerably lower;

This results in a significant over-estimation of potential for glucose consumption and resulting level of gluten in one sitting, even taking into account a precautionary approach..
The level that can be technically and practically achieved when using the methods as given in Appendix 2 is an average and to always achieve a level of 10mg/kg will require measures over and above those required by this method and a commensurate additional processing cost to be imposed on local manufacturing.

For example, Table 6 Calculation of the amount of glucose syrup and food (confectionery or chocolate) containing 1mg wheat protein at three different gluten levels (mg/kg)

Upper limit of wheat protein consumed from glucose syrup in one sitting	Level of gluten in glucose syrup	Amount of glucose syrup containing 1mg wheat protein (gluten=75% total wheat protein)	Amount of food containing 1mg wheat protein (assuming 50% glucose syrup in food)
1 mg	20mg/kg	37g	75g
1 mg	10mg/kg	75g	150g
1 mg	5mg/kg	150g	300g

This table makes the assumption that all Glucose syrup from wheat are manufactured to have the maximum level of gluten specified – whereas both the surveys in EU and also in the local market have demonstrated this is not the case.

The point this table does not consider, is that the manufacturing method for glucose produces glucose where in the majority of cases, it results in the gluten level being below the LOD (as was determined in EU). We are concerned at some of the data provided about Australian produced glucose syrup as this is not consistent with our understanding. We welcome the opportunity to work with the local manufacturer to provide FSANZ with this data. And using data from the local manufacturer, when taking a precautionary approach using conservative figures, below 10mg/kg 80% of the time and below 20mg/kg the rest of the time. This results in average gluten level for glucose syrup of 12mg/kg.

Upper limit of wheat protein consumed from glucose syrup in one sitting	Level of gluten in glucose syrup	Amount of glucose syrup with gluten level	Amount of food containing 1mg wheat protein (assuming 50% glucose syrup in food)	Amount of glucose syrup containing 1mg wheat protein (gluten=75% total wheat protein)
1mg	20mg/kg	20%	75g	37
1mg	10mg/kg	80%	150g	75
1mg	12mg/kg	Average	125g	62.5

2. The FSANZ risk assessment has determined consumption of wheat-derived glucose syrup that had been purified and prepared as described in the process (with a gluten content of 10-20mg/kg) is likely to present negligible risk to the majority of wheat allergic consumers. The level of protection for 10mg/kg compared to 20mg/kg is not significantly different, and requiring compliance to a 10mg/kg level will impose additional costs on both local manufacturers and also for importers to require an extra level of compliance over and above what is required in EU where compliance for Glucose syrup is set up for less than 20mg/kg.

3. The level recommended to ensure that gluten levels in glucose syrup are as low as technically achievable, are not internationally consistent again imposing an additional barrier of compliance and cost for ANZ industry who consider use of the

exemption is a step towards improved alignment with EU exemptions.

Responses to FSANZ questions:

1. Is there further information about allergic consumers and health and safety aspects that you would like to provide for consideration?

As part of Allergen Bureau working relationships with key stakeholders, we have proactively drawn attention to this proposal and encouraged the relevant consumer and in particular, allergic consumer organizations to engage with this proposal – please see listed below the organisations we have contacted to encourage input at this consultation opportunity:

- Allergy & Anaphylaxis Australia
- Allergy New Zealand
- Coeliac Australia
- Coeliac New Zealand

2. Is there further information about production methods and/or residual protein levels of the substances discussed that you would like to provide for consideration?

Manildra will be providing further information about production methods, associated residual gluten levels and the impact of the proposed 10mg/kg limit. This information is relevant for local manufacturing and how local supply chain would be impacted by this proposal.

3. Do you have suggestions as to preferred means of communicating these changes to interested parties?

We believe the most effective means of communicating these changes is by developing agreed briefing sheet with FSANZ, industry and allergy organizations. An effective mechanism for this could be through the Allergen Collaboration. It will be important for allergic consumers to have confidence in this changes and consistent communication from the range of sources will assist this.

4. Are there other implications for interested parties from the proposed exemptions from allergen declarations that may require consideration? If so, please provide any suggestions you may have as to how these might best be managed?

5. Do you have further considerations to add to the cost benefit analysis?

There is one point we would like to raise that has been included in the Cost Benefit analysis:

Harmonisation with international regulations could reduce the need for companies selling to multiple markets to produce different labels.

One consideration for the allergen labelling exemption is the impact for local manufacture, however these exemptions will also be applicable to imported products

with glucose as an ingredient. This is currently an area of labelling inconsistency with products sourced from Europe and a key driver for promoting a consistent approach internationally. At this time, the other major regulatory body with Allergen Labelling Exemptions is EU, with USA and Canada considering how to move forward with an approach. For this reason, we are strongly supportive of international alignment for labelling exemptions.

For imported products, information on the glucose ingredient will need to be provided by the supplier of this ingredient to meet the manufacturer's requirements.
For product manufactured in EU, the product specification is set to meet 20ppm – this is established as the limit within the supply chain between the glucose manufacturer and the customer.

For a 10ppm gluten limit, additional testing and information will need to be put in place by the glucose supplier to meet this requirement, over and above what is required to meet the EU requirements of demonstrating compliance with 20ppm gluten limit. Therefore this additional process would need to be set up for any products being imported into ANZ:

- For products manufactured with glucose syrup as a direct ingredient;
- For products containing compound ingredients containing glucose syrup, etc.

As this is not a determination based on the final product, what it will mean is that glucose syrup suppliers would need to test to 2 levels – 20ppm for EU requirements AND 10ppm for ANZ requirements – this will be difficult to implement (for small ANZ volumes, we are sometimes unable to justify the business case to put these additional steps in place) and if was able to be put in place, additional costs would be put to the ANZ business.
For the current situation without the exemption in place, we now have to have a separate label for ANZ products (some EU countries are not permitted to put additional information on the label that gives different safety status).
With the proposed 10mg/kg level, we would then have two possible scenarios:

a) We can set up an additional ANZ only 10ppm limit compliance requirements through the supply chain– in which case we have support for the exemption and can use common labels with EU from a Glucose syrup labelling perspective – no need to label (from wheat) OR
b) If the 10ppm information cannot be obtained through the supply chain, we would not have the support required to implement the exemption and we would have to remain with the existing separate label that states glucose syrup(from wheat) – therefore consumers would not see the benefit of clearer risk based labelling on these products.

The proposed level of 10mg/kg is not aligned with how the EU glucose exemption has been implemented in practice, and proposing the 10mg/kg level imposes additional compliance costs on ANZ industry

6 . Do you agree/disagree with the proposed exemptions?

We agree and support the four proposed allergen labelling exemptions.

We do not support the proposed condition for glucose syrup from wheat starch to be exempted from mandatory allergen labelling where the residual gluten content is less than or equal to 10mg/kg.

Conclusion:

In conclusion, we are supportive of the risk assessments and the risk management recommendations for each of these three products as they have resulted in proposed exemptions that are evidence based and are internationally consistent (aligned to those already in place in European Union) and do not propose unique Australian/New Zealand compliance requirements or additional costs.

The Allergen Bureau Allergen supports the proposed exemption for allergen labelling for Glucose Syrup from Wheat however we do not support the reasoning and recommendations for a residual gluten content to be less than or equal to 10mg/kg and we request serious reconsideration of this proposed level, with consideration of good manufacturing process and/or a more internationally consistent gluten level of 20mg/kg.

[redacted]
Allergen Bureau Director
Lead for Allergen Bureau Allergen Labelling Exemptions Working Group