FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 3

Summary of submissions – Proposal P1031

Allergen Labelling Exemptions

Issue	Raised by	FSANZ response (including any amendments to drafting)
A&AA strongly supports the activities of the Allergen Bureau and appreciates any steps taken by FSANZ to improve allergen labelling. Nonetheless there is no apparent consideration of the other priorities of those afflicted with food allergies, by direct consultation with organisations such as A&AA or by other means. The proposal may well provide a benefit to industry but there is no apparent major benefit to consumers arising from the proposed amendments. The exemptions proposed are somewhat less than the EU exemptions, and do not include exemptions such as glucose syrup made from barley. This could expose FSANZ to inferences of facilitating international competitiveness for local industries at the expense of EU industries. This would apply, for example, in the case of EU industries either making glucose syrup from barley, or using such glucose syrup in other products.	Allergy & Anaphylaxis Australia (A&AA)	Further consultation has been undertaken with A&AA since the CFS. The exemptions proposed for consideration were arrived at following extensive consultation with industry, consideration of available evidence and practical implications. Complete harmonisation with Europe was not a driving factor, and in particular harmonisation in respect of gluten-related foods (eg barely syrups). FSANZ acknowledges the list is not exhaustive. Benefits to consumers are increased choice of foods which may have previously been avoided due to allergen declarations indicating unsuitability. FSANZ acknowledges other foods/ ingredients may warrant consideration in due course and the application pathway is open to stakeholders wishing to pursue any such foods or ingredients.
The structure of the amendment could exempt the declaration of the proposed exempted foods or substances in toto, including in an ingredient list, or at the least may appear to do so. For example, Standard 1.2.3—4 (1) requires anything listed in that subsection to be declared. Then subsection (b)(i) lists cereals etc and their products “other than (B) glucose syrups...not exceeding 10mg/kg”, thus exempting such glucose syrups from declaration altogether.		The structure of the amendment for glucose syrups from wheat is appropriately drafted for its intent to exempt only the mandatory allergen declaration (in this case wheat). The provisions of Standard 1.2.3 do not override those of Standard 1.2.4 – Labelling of Ingredients. Therefore, glucose syrups would still be required to be listed along with

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A&AA assumes this is not the intent of the proposal, and the proposed amendment should be redrafted accordingly to make the intention perfectly clear to businesses endeavouring to comply with the Code. A&AA is reluctant to support any proposed amendments which would appear to relax in any way industry's obligations to provide full and detailed declaration of the source of each product's ingredients, unless the changes are unambiguous, enforceable and present a clear benefit to both industry and consumers. Specific comments provided on: • soybean oil that has undergone a complete refining treatment - it is unclear how it could be enforced and how complete refining is measured; non-compliance will only be evident when a reaction is suffered. • tocopherols and phytosterols derived from the deodoriser distillate of fully refined soybean oil – is FSANZ confident these can only be derived from distillate? • glucose syrup derived from wheat starch – how consistently is <10 mg/kg achieved? • alcohol distillate made from wheat or whey – concerns regarding possibility of poorly controlled distillation resulting in residual protein and lactose • vinegar [from wheat] – it is not clear how this is relevant to the proposal, or how the amendment provides declaration exemption. Whilst A&AA could support the proposed amendments if its concerns were fully addressed, A&AA would prefer that FSANZ had directed its resources towards the myriad of unresolved shortcomings already identified in the allergen labelling requirements.		other ingredients as per Standard 1.2.4. Concerns regarding effectiveness and suitability of processing methods, such as oil refinement and distillation processes, are largely self-managed by the necessary quality parameters for suitability for use and fit for purpose products. There are international standards and accepted methodologies in place for refinement of oils such as through the N/RBD process which are well understood and accepted throughout the world as being required before soybean oil can be called 'fully refined'. Whilst for some products there may be residual components such as protein, the risk assessment has identified these as not being at clinically significant levels. Adverse reactions as a result of non-compliance are a matter for monitoring and enforcement by the jurisdictional agencies responsible. To this end the proposed variation for wheat derived glucose syrups has been amended to address technical and compliance practicalities. The Risk Assessment report discusses vinegar derived from whey alcohol (not wheat) and grain alcohol products, in general, produced from wheat starch. This is relevant to the Proposal as such vinegars have been found to contain no detectable beta lactoglobulin and hence, would be exempt from the declaration of milk and milk product declaration required under Standard 1.2.3. Other allergen related issues such as those highlighted in the submission are currently being considered by FSANZ through other pathways.

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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 no demonstrable consumer food safety benefit. Detailed technical arguments were provided from the Allergen Bureau Allergen Labelling Exemptions working group (pages 6-8) in support of their position.	Allergen Bureau	Further consideration has been given to the proposed approach to exemption of glucose syrups from wheat starch. The variation has subsequently been amended on the basis of new evidence regarding technical achievability and the cost implications to industry of the risk management approach proposed in the CFS.
Allergy New Zealand supports the proposal, based on the assessed risk to consumers with food allergies as 'negligible'; and that it will lead to greater choice for consumers. Recommend FSANZ develop a communication paper with the input of clinicians and consumer organisations, which we can use to advise our networks and educate consumers with food allergy accordingly.	Allergy New Zealand	FSANZ anticipates a collaborative approach with government and non-government agencies as appropriate for dissemination of information regarding the Code variation
The AFGC supports the proposal to exempt certain foods and ingredients derived from allergenic foods from mandatory declaration of allergens where available evidence indicates the production methods used remove or reduce allergenic proteins to levels that are of negligible risk to allergic consumers. The AFGC recommends that FSANZ reconsider the proposed approach for glucose syrup derived from wheat starch and remove the limit or provide a limit of 20ppm. Provided the following technical arguments in support of their position:	Australian Food and Grocery Council (AFGC)	Further consideration has been given to the proposed approach to exemption of glucose syrups from wheat starch. The variation has subsequently been amended on the basis of new evidence in respect of technical achievability and cost implications. The amended variation allows for harmonisation with food trade from Europe.

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• FSANZ have concluded that there is a similar level of risk for 10-20mg/kg of gluten therefore the lower level provides no greater level of protection; • The dietary modelling is very conservative. The modelling assumes that confectionery or chocolates all contain 50% glucose syrup, even for modelling purposes doing so inflates the results. The only products that exceed 50% glucose syrup are hard boiled confectionery (55%) and marshmallows (67%), all other examples provided are significantly less. • 100g seems to be an arbitrary figure. It's a quarter more than the 97.5th percentile for chocolate (75g), and almost 10% more than confectionary (91g). FSANZ have acknowledged that the daily consumption data for the 97.5th percentile is likely to be an overestimate as it was taken to represent a single meal. • The local manufacturer does NOT support the 10mg/kg level - being required to operate at this level will impose significant extra cost, where there is no demonstrated benefit; and • The level is inconsistent with the EU labelling exemption in practice – a region that relies heavily on wheat-based glucose syrup similar to Australia and New Zealand.		The dietary modelling underpinning the risk assessment has been revised to incorporate new information from industry on uses of glucose syrup in confectionery, chocolate and ice cream, the most recent Australian food consumption data from the 2011-13 Australian Health Survey and New Zealand food consumption data from the 2002 Children's Nutrition Survey and the 2008-09 Adults Nutrition Survey . The outcome of these updates is that the amount of chocolate and confectionery reported as consumed in these surveys is higher than that previously reported, which has an impact on the risk assessment. For example, the 97.5th percentile of consumption for consumers of chocolate is 100 -183 g/day for Australian children aged 2-4 years and 5-14 years respectively and 100 g/day for New Zealand children aged 5-14 years. Consumption of confectionery at the 97.5th percentile ranges from 52 g/day for Australian children aged 2-4 years to 232 g/day for New Zealand children aged 5-14 years The revised risk assessment recognises that not all confectionery will contain 50% glucose syrup and that in New Zealand the sole manufacturer of glucose syrups meeting 90% requirements for glucose syrup produces a corn-based glucose syrup. It is also noted that some imported confectionery contains glucose syrup derived from corn or tapioca.
The Ai Group Confectionery Sector supports in principle Proposal P1031 to allow for specific exemptions from mandatory allergen declarations where available evidence indicates the production methods used remove or reduce allergenic proteins to levels that are of negligible risk to allergenic consumers. The Ai Group Confectionery Sector supports the proposed exemption from	The Australian Industry (Ai) Group Confectionery Sector	

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labelling for fully refined soybean oil, tocopherols and phytosterols derived from soybean based deodoriser distillate, alcohol distillates from wheat or whey, and for wheat-derived glucose syrup but does not support the proposed limit of ≤10 mg/kg. The confectionery industry proposes that FSANZ reconsider the approach for glucose syrup derived from wheat and approve no upper limit for gluten in line with good manufacturing processes, consistent with international regulatory practice, risk and cost effectiveness, and failing that, the set the limit at 20 mg/kg and not 10 mg/kg. Provided detailed technical arguments in support of their position: Level of risk FSANZ risk assessment concluded that the level of protection associated with wheat-derived glucose syrup with gluten content of 10 to 20 mg/kg is similar. <u>International consistency</u> The proposed Australia/New Zealand allergen labelling exemption for wheat-derived glucose syrup with gluten content ≤10 mg/kg is not consistent with the European Union (EU) labelling exemption. <u>Cost effectiveness</u> It is understood that the gluten in Australian glucose syrup is mostly ≤10 mg/kg and a local glucose manufacturer has indicated that in order to consistently achieve glucose syrup with gluten content at the level proposed by FSANZ will impose significant extra cost, without demonstrated benefit. The proposed gluten level of ≤10 mg/kg will add production costs, establish requirement for differential product standards for domestic and export markets as well as increased testing and adds no tangible benefit for the consumer. Additionally, to manufacture glucose syrup consistently to the more restrictive proposed Australia/New Zealand standard further disadvantages the producers' competitiveness in export markets. <u>Consumption data</u> The dietary exposure assessment used by FSANZ is based on: - an arbitrary consumption amount of 100 g representing a single eating occasion,		Further consideration has been given to the proposed approach to exemption of glucose syrups from wheat starch. Discussions with glucose syrup producers and importers identified difficulties in working to the European approach of a code of practice that would lead to enforcement problems for Australia and New Zealand therefore, this approach was not pursued. On the basis of new evidence in respect of technical achievability and cost implications the variation has been amended to allow for residual gluten levels up to 20 mg/kg. This also allows for harmonisation with food trade from Europe. The consumption data and rationale for the associated assumptions are detailed in the Risk Assessment provided as SD1.

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- assumptions regarding the levels of glucose syrup in confectionery, and - assumptions that all glucose syrup in confectionery is always from wheat. The likelihood of all confectionery products containing glucose syrup with 20 mg/kg gluten and 50% wheat-derived glucose syrup is therefore unlikely. <u>WTO obligations</u> The recommended level of ≤10 mg/kg is not internationally consistent and will therefore continue to be a barrier to trade.		The dietary modelling presents a 'worst case scenario' and uses industry data for inclusion of glucose syrups in confectionery and ice-creams, three scenarios are modelled: maximum of 10% glucose syrup (ice-cream), 30% (filled chocolates and confectionery) and 50% (some confectionery). The modelling has been revised on the basis of new data provided by industry and to incorporate the 2011-13 Australian Health Survey data and New Zealand consumption data.
Australia New Zealand Distillery Ltd support exempting alcohol from whey (and products thereof) from requiring an allergen declaration. We would want the exemption to cover distillates from whey and further derivatives of that distillate. We believe that as there is strong analytical evidence that distilled alcohol and vinegar derived from whey present negligible risk to milk allergic individuals, the exemption should proceed in a similar manner to what has occurred in the EU.	Australia & New Zealand Distillery Limited	Further derivatives of distillates, such as vinegars, are covered by additional drafting in Attachment A (new section 1.2.3—4(3) to make it quite explicit that these products are covered by the exemption.
The Brewers Association is of the view that this Proposal: • Does not adversely impact on consumer health and safety • Offers benefit to consumers by increasing product choice • Assists manufacturers by simplifying increasing demands on label space • Improves manufacturing flexibility • Is generally consistent with international approaches.	Brewers Association of Australia and New Zealand	Noted
Coeliac Australia does not support the proposal - has concerns in two main areas: By exempting wheat derived glucose syrup from the mandate to declare its allergenic source, gluten free consumers will no longer be provided with adequate information to make an informed food choice. Consumers do have a right to know what is in their food; the changes proposed in P1031 would likely cause consumer uncertainty and distrust. The provision that glucose syrup made from wheat starch be exempted from mandatory allergen declaration requirements where the residual gluten content is less than or equal to 10 mg/kg effectively allows an ingredient that contains detectable levels of gluten to be included in a food product, without any declaration. We believe this contradicts the essence of standard 1.2.7	Coeliac Australia (CA)	The impact of the proposed draft variation will be to exempt the declaration of wheat in respect of glucose syrups where assessed under Proposal P1031 as presenting negligible risk. The variation to Standard 1.2.3 as a result of this proposal is not intended to have any effect on the current provisions for gluten-related labelling, including those contained in Standard 1.2.7. Moreover, the gluten-free issue is

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relating to gluten claims and [we] are concerned about the potential for the consumer to be misled.		addressed by consumer law that requires claims of 'free' to be analytically so, and not misleading.
When dealing with setting levels of gluten, allergens should not be looked at in isolation; consideration must also be made for other severe reactions to this protein, especially coeliac disease. Exposure to gluten may not cause an immediate 'anaphylaxis-type' reaction in those with coeliac disease, however coeliac disease is a serious condition where exposure to even the tiniest trace of gluten can result in a variety of horrific short term reactions and cause long-term chronic illness in sufferers. Expressed concerns about the proposal regarding glucose syrup derived from wheat. Recommend consultation with gastroenterologists should also be required before any proposal of this nature is accepted by FSANZ. It is unclear as to whether Australian manufacturers actually support the proposed limit of 10 mg /kg level or not. A number of statements in the Proposal make it difficult to come to a conclusion as to what levels are best for industry and the consumer. There is no reference to the self-regulation of gluten levels within the industry. Gluten affects the clarity and quality of the syrup. The more gluten, the cloudier (and more inferior) the syrup. It is the quality of the syrup which drives manufacturers to keep it this low, not a regulated threshold of gluten. The 'birthday party scenario' (p5) is misleading and should not be extrapolated to the whole population of 'wheat sensitive individuals' (which would include those with coeliac disease) as: a. Not all confectionery contains glucose syrup derived from wheat b. A one-off scenario is not the best way to generate a society norm c. 7-16 year olds are not a true representation of the population d. It should not be assumed that all confectionery containing glucose syrup derived from wheat has same % of glucose syrup and ratio of total protein to gluten. The difference in Gluten Free labelling laws (i.e. FSANZ – no detectable gluten vs. CODEX ≤20 mg/kg) is already confusing enough for manufacturers, gluten	Coeliac New Zealand	As described in the risk assessment the primary consideration under P1031, in respect of wheat derived glucose syrups, is the safety of wheat allergic consumers. However as also discussed in that report such syrups would also be suitable for those with coeliac disease. The risk assessment for Proposal P1031 was guided by the advice of an expert advisory panel comprising allergen specialists drawn from Australia and New Zealand. These clinicians routinely manage patients with coeliac disease and related gastroenterological issues. FSANZ acknowledges the industry-based quality parameters of clarity and colour in glucose syrups. Whilst these parameters cannot be directly used for purposes of regulating gluten protein levels, they are loosely aligned and thereby complementary by way of providing further drivers for highly refined glucose syrups. The intent of the dietary modelling was to present a 'worst case scenario' for consumption of confectionery, chocolate or ice-cream at a single sitting. As such, and from a safety perspective, it could be said extrapolation to the general population provides a conservative rather than misleading view. This would be especially the case for those with coeliac disease.

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free consumers and the medical profession. To impose an additional threshold level of ≤10mg/kg specifically for glucose syrup derived from wheat will only lead to further confusion. There must be a consistent approach across all manufactured products. Does not agree that the proposed *"glucose syrup made from wheat starch be exempted from mandatory allergen declaration requirements where the residual gluten content is ≤10 mg/kg"* (p9) be accepted. Recommends that exemption from labelling be granted to products containing glucose syrup derived from wheat, however does not support the proposed limit of 10 mg/kg. If a specified limit is required, then it should be ≤ 20 mg/kg in line with EU regulations.		The variation to Standard 1.2.3 as a result of this proposal is not intended to have any effect on the current provisions for gluten-related labelling, including those contained in Standard 1.2.7. Moreover, the gluten-free issue is addressed by consumer law that requires claims of 'free' to be analytically so, and not misleading. The Code variation has been amended to such that glucose syrup made from wheat starch be exempted from mandatory allergen declaration requirements where the residual gluten content is less than 20 mg/kg.
Dairy Australia supports the proposal to exempt the identified four products, soybean oil that has undergone a complete refining treatment, tocopherols and phytosterols derived from the deodoriser distillate of fully refined soybean oil, glucose syrup derived from wheat starch, and alcohol distillate made from wheat or whey from mandatory labelling requirements for allergen. When considering the promotion of consistency between domestic and international food standards we note that the proposed residual gluten content limit for glucose syrup made from wheat starch to be exempted from mandatory labelling is proposed to be set at <10mg/kg. This level is significantly inconsistent with international food standards of < 20 mg/kg. Dairy Australia suggests that further data should be sourced from international jurisdictions with current <20 mg/kg limit and producers of glucose syrup made from wheat starch for further consideration to ensure a limit is set that is: evidence based; outcomes focussed; proportionate to risk; whilst still supporting and promoting trade and competition, and the benefits outweigh the costs.	Dairy Australia	A more harmonised international approach to risk management of wheat derived glucose syrups has been addressed through amendments to the proposed variation whereby allergen declaration exemption for wheat derived glucose syrups is subject to residual gluten protein levels of <20 mg/kg. Further consideration has been given to the proposed approach to exemption of glucose syrups from wheat starch. The variation has subsequently been amended on the basis of new evidence in respect of technical achievability and cost implications. The amended variation allows for harmonisation with food trade from Europe.
DGC fully supports the recommendations of this FSANZ proposal. We agree that it is sensible to exempt foods and ingredients derived from allergenic foods from mandatory declaration of allergens where risk assessments conclude this will present negligible risk to allergic consumers. The key benefit will be a wider range of products available to allergic consumers	Dairy Goat Co-operative (N.Z.) Ltd (DCG)	

Issue	Raised by	FSANZ response (including any amendments to drafting)
and there will also be significant benefits to industry in relation to allergen management. We encourage FSANZ to apply this same approach to other foods and ingredients that may similarly warrant close examination with respect to mandatory allergen labelling, for example lecithin derived from soy particularly where used at low levels. The proposals are of considerable importance to allergic individuals as well as manufacturers. It is important that the communication plan developed reaches and informs both of these groups. A key point that needs to be emphasised for both these audiences is that not all soy oils or soy derived tocopherols and phytosterols are exempt. For these foods/ingredients the processes they have undergone are key and dictate whether they are exempt or not. Suggestion provided in relation to the proposed wording for the draft standard revision in order to clarify intent.		FSANZ anticipates a collaborative approach with government and non-government agencies as appropriate for dissemination of information regarding the Code variation to all impacted stakeholders FSANZ has given consideration to and discussed with DCG the suggested amendments to the draft variations. The suggested amendments as proposed were not considered necessary.
The Department supports the exemption of these products if they meet the appropriate production methods and/or maximum level as is the case for gluten in glucose syrup derived from wheat starch (gluten <10 mg/kg). Question 3 in the submission asks for suggestions on the preferred means of communicating these changes to interested parties. The most effective way to communicate changes would be via key allergy organisations websites and health professional channels. These include but are not limited to Allergy and Anaphylaxis Australia, Australasian Society of Clinical Immunology and Allergy, FSANZ, Dietitians Association of Australia, Coeliac Australia and Primary Health Networks. These organisations can then use their usual channels of communication to pass the changes on allergen declaration to allergic individuals.	Department of Health and Human Services, Tasmania	FSANZ is appreciative of assistance from the various organisations and agencies that may be able to assist in a collaborative approach to best communicating respective changes to interested parties.
DAA supports the proposed amendments to exempt the following food and ingredients from mandatory labelling requirements for allergens: • Soybean oil that has undergone a complete refining treatment • Tocopherols and phytosterols derived from the deodoriser distillate of fully refined soybean oil • Alcohol distillate made from wheat or whey. DAA supports the proposed amendments to exempt glucose syrup from wheat starch from mandatory labelling requirements, however recommend the proposed limit is increased to 20 mg/kg (ppm).	Dietitians Association of Australia (DAA)	

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Some concern was expressed by a DAA member about the risk to the public if the oils used in food manufacturing change due to various issues such as supply or cost and a less refined oil is substituted, resulting in a higher level of protein contaminant. DAA recognises that this is an issue for jurisdictions in monitoring and surveillance of the implementation of the Food Standards Code, rather than for FSANZ itself. In regards to the labelling exemption for glucose syrup derived from wheat starch, DAA recommends increasing the proposed limit of 10ppm, to a maximum level of 20 mg/kg of residual gluten for the following reasons: • FSANZ outlined in the submission document that • "Based on the available clinical evidence and likely single meal consumption, FSANZ concluded that wheat-derived glucose syrup with a gluten content of 10-20 mg/kg is likely to present a negligible risk to the majority of wheat allergic individuals". • This will allow consistency with EU allergen labelling, which permits "gluten-free" foods with maximum 20 mg/kg gluten in the food as sold to the final consumer. • Local manufacturers of glucose syrups do not support the proposed limit of 10ppm as this level will impose significant extra cost on their business in order to continue to operate in the local and global markets. The following organisations can disseminate the information to their members: • Australian Society of Clinical Immunology and Allergy • Dietitians Association of Australia • Anaphylaxis Australia • The Coeliac Society • Australian Medical Association • Australian Food and Grocery Council • Schools • Baby health centres FSANZ could produce a pamphlet that can be provided to primary sources of nutrition education (e.g. Accredited Practising Dietitians, doctors, paediatric health nurses) to give to consumers. FSANZ should also consider public advertising. DAA supports the exemptions as:		Less refined oils, and cold pressed oils will not qualify for the exemption. Effective refinement of soy oils is required from a quality perspective for sale as food grade oils and therefore most soy oils will be able to be exempt from labelling because meeting the quality parameters will also mean they contain protein at levels which are in compliance with the standard. Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended variation. FSANZ is appreciative of assistance from the various organisations and agencies that may be able to assist in a collaborative approach to best communicating changes to interested parties and has developed a communication plan.

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• Consumers with allergies will benefit from a larger range of food choices. • Nutrition educators, such as Accredited Practising Dietitians, will have more time to educate clients on allergen free diets rather than explaining labelling laws.		
DSICA fully support the exemptions for distilled alcohol from wheat and whey. Support the need for less burdensome and appropriate labelling, considering [current] requirements are overly restrictive and may lead to unnecessarily restricted diets, risk-taking behaviour and increased consumer frustration eg consumers ignore warnings on the basis of prior consumption of product without an adverse reaction. Agree with the analysis that all parties will benefit.	Distilled Spirits Industry Council of Australia (DSICA) (LATE COMMENT)	Noted
Supported the exemptions	Distilled Spirits Council of US	Noted
Fonterra is supportive of the proposal to exempt certain foods and ingredients derived from allergenic foods from mandatory allergen declarations where evidence indicates the production methods used remove or reduce allergenic proteins to levels that are of negligible risk to allergenic consumers. We note there is a difference in the FSANZ suggested maximum level of gluten for glucose syrups from wheat starch at ≤10 mg/kg for exemption from allergen labelling declaration when compared to the gluten-free definition for foods specifically processed to remove gluten, including wheat, as prescribed by Codex Stan 118-1979 (Amendment 2015) and EC No 41/2009 at <20 mg/kg.	Fonterra	The variation under Proposal P1031 is not intended to address the gluten-free definition or labelling provisions for Australia and New Zealand.
FBIA support exemptions but do not agree with the proposed condition that the residual gluten content be less than or equal to 10 mg/kg. This Proposal does not give sufficient weight to the role of good manufacturing practice (GMP), as described in the Call for Submission, and is not consistent with generally accepted international exemption level of 20 mg/kg. The proposed level of 10 mg/kg has the potential 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. We request that the 10 mg/kg gluten level be reconsidered.	Food and Beverage Importers Association (FBIA)	Serious consideration was given to using GMP or a code of practice as a risk management strategy however, for various reasons this was not seen as practical for industry or enforcement. Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended draft variation.
FTA agreed with the draft variation except that in Standard 1.2.3 (b) the Glucose	Food Technology	Increasing the proposed limit of residual gluten in glucose

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Syrups made from wheat starch should be permitted to have a gluten content not exceeding 20 mg/kg, in agreement with current CODEX and EFSA-2014 Standards	Association Australia	syrups from 10 to 20 mg/kg has been addressed in the amended draft variation.
GLNC supports the proposed exemptions and has no further comments in relation to: - soybean oil that has undergone a complete refining treatment; - tocopherols and phytosterols derived from the deodoriser distillate of fully refined soybean oil; and - alcohol distillate made from wheat or whey. GLNC supports an exemption from labelling for glucose syrup derived from wheat starch but does not support the proposed limit of 10 mg/kg (ppm). GLNC recommends that FSANZ reconsider the proposed approach for glucose syrup derived from wheat starch and remove the limit or provide a limit of 20 mg/kg. Provided the following technical arguments in support of their position: • The lower level of 10ppm provides no greater level of protection and imposes an unnecessary restriction on manufacturers of glucose syrups from wheat which would in turn impact manufacturers of grain based food products containing glucose syrup derived from wheat starch, such as selected breakfast cereals, grain based bars, biscuits, crackers and crispbreads. • FSANZ concluded, “Based on the available clinical evidence and likely single meal consumption …. that wheat-derived glucose syrup with a gluten content of 10-20 mg/kg is likely to present a negligible risk to the majority of wheat allergic individuals.” • A large body of evidence from studies on consumers with Coeliac Disease demonstrates diets containing the small, but measurable amounts of gluten, at levels found in current ‘gluten free’, including ‘naturally gluten free’ products lead to healing of the intestinal mucosa. The totality of the data point to a maximum tolerated daily intake higher than 10 mg, but lower than 100 mg/day and indicate that wheat starch-based food is safe, provided it contains <100 mg gluten/kg. • In relation to wheat allergy - comparing the recommended Vital Reference Dose for IgE mediated wheat allergy to potential thresholds for gluten free labelling, the Codex guideline for gluten free of <20 mg/kg (ppm), wheat-allergic consumers would be largely protected when selecting gluten free	Grains & Legumes Nutrition Council (GLNC)	Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended draft variation.

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products manufactured in conformity to Codex guidance. Assuming all of the protein is gluten, 20 mg/kg corresponds to the Reference Dose (1.0 mg) in a 50g serving of food. These findings are consistent with those reported by FSANZ and support the safety of 20 mg/kg for both coeliac and wheat allergic consumers. • The level is inconsistent with the EU labelling exemptions. • The proposal to set a limit of 10 mg/kg (ppm) is not consistent with the EU labelling exemption in practice where a level of 20 mg/kg of residual gluten is accepted in line with the Codex requirement for gluten free claims. As such the Proposal does not support the promotion of consistency between domestic and international food standards or the promotion of fair trading in food with respect to setting the limit for glucose syrup derived from wheat. From discussions with the Australian Food and Grocery Council, GLNC understands a limit of 10 mg/kg will likely impose significant extra cost on Australian business in order to continue to operate in both the local and global market.		
Lion supports the proposed change to exempt certain foods and ingredients derived from allergenic foods from mandatory declaration of allergens, in particular distilled alcohol from wheat or whey.	Lion	Noted
Manildra supports the proposal to exempt certain foods and ingredients derived from allergenic foods from mandatory declaration of allergens where available evidence indicates the production methods used remove or reduce allergenic proteins to levels that are of negligible risk to allergic consumers Manildra supports an exemption from labelling for glucose syrup derived from wheat starch but does not support the proposed limit of 10 mg/kg (ppm). Manildra requests that FSANZ reconsider the proposed approach for glucose syrup derived from wheat starch and approve a limit of 20 mg/kg. Manildra does not support the proposed limit of 10ppm for the following reasons: • The level proposed will impose significant extra cost, where there is no demonstrated benefit; • There is a similar level of risk for 10-20 mg/kg; and • This is not consistent with the EU labelling exemption in practice – a region that relies heavily on wheat-based glucose syrup similar to ANZ. <u>Cost Impact</u> The additional cost of manufacturing, segregation of product between local and	Manildra Group	FSANZ has further consulted with Manildra regarding technical issues and costs. Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended draft variation.

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exported product and additional testing would impose an additional cost to the business which would be added to the product price. In a commodity marketplace, this will have a significant impact on our competitiveness. Manildra would be willing to provide further detail around the cost impact to assist FSANZ (this has occurred). <u>Level of Risk</u> As stated in the P1031 Proposal the difference in risk to wheat allergic consumers between 10 mg/kg (ppm) and 20 mg/kg is negligible. <u>International Consistency</u> Currently we compete with European glucose manufacturers who export to Asia. These manufacturers comply with CODEX [gluten-free] limit which is < 20 mg/kg (ppm). This level is widely accepted throughout Asia. <u>Alternative Approach</u> Manildra propose that for glucose syrups from wheat the limit should be set at 20 mg/kg and not 10 mg/kg for the reasons outlined in our submission. The proposed limit of 10 mg/kg will place our business at a significant disadvantage in the export market with no corresponding increase in food safety.		Changes to the variation will facilitate competitiveness with Europe and trade into Asia.
Mondelez Australia supports P1031 “Allergen Labelling Exemptions” in principle but would like to raise a concern regarding the level of gluten in glucose syrup derived from wheat starch. Our “in principle” support is based on providing those with an intolerance to wheat protein and gluten with a wider range of foods that are not required to be labelled as coming from a wheat source but we have significant concerns with the rationale behind the P1031 recommendation. Understands that the EU (Commission Directive 2005/26/EC) provides an exemption from labelling for wheat based glucose syrups with no limitations on the gluten. This Proposal would mean that we are out of step with existing international legislation. Coeliacs, and those with a wheat protein intolerance, are no less or more sensitive in the EU than in Australia and New Zealand Considering that the Proposal states that the majority of the wheat glucose	Mondelez Australia	The proposed risk management approach is that the glucose syrup (ie the ingredient) would only have to declare wheat if it contains equal to or more than 20 mg/kg gluten protein. Assuming the syrup is then used as an ingredient there would then be carryover labelling to the final product. This would apply regardless of how much is used in the final product. However from what we understand of the production methods, it is highly unlikely any food grade glucose syrup will contain this much gluten protein.

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syrup available in Australia is <10 mg/kg (and as stated in part 2.1.3 95% of samples tested were below the detectable level of 3 mg/kg) the likelihood that consumers would consume confectionery manufactured only with wheat glucose syrup at 20 mg/kg is highly unlikely. Also as the 50% Glucose syrup usage is at the maximum level the impact is going to be even lower again. The additional anomaly is that if we were to manufacture a product that contained 25% glucose syrup at 20 mg/kg gluten it would contain the same level of gluten as a product made with 50% glucose syrup at 10 mg/kg/gluten – yet in accordance with the recommendation of this Proposal we would have to declare that the glucose syrup containing 20 mg/kg gluten was from a wheat source. Similarly a product made with a blend of wheat glucose syrup at 20 mg/kg and corn derived glucose syrup could contain less gluten than a product made wholly with glucose syrup at 10 mg/kg gluten. If, as stated in part 2.2.2.3 "FSANZ concluded that wheat-derived glucose syrup with a gluten content of 10-20 mg/kg is likely to present a negligible risk to the majority of wheat allergic individuals" and as stated in 2.1.3 "Analytical data from Australian produced glucose syrup shows that in 95% of samples tested, gluten levels were below the limit of detection (<3 mg/kg)" why does the Proposal seek to set a limit on having to declare wheat as the source of a glucose syrup at a maximum 10 mg/kg?		The intent of the dietary modelling was to provide a 'worse case' scenario for consumption of confectionery, chocolate or ice-cream at a single sitting. The modelling included estimates of the maximum amount of food that could be consumed before the threshold level for wheat protein is reached at various concentration levels of gluten in glucose syrup, which illustrates the point made here and the inverse relationship between the amount of food that can be consumed and the gluten concentration. FSANZ recognises that the level of gluten in glucose syrup may not be constant and that some products will contain glucose syrup derived for corn or tapioca.
NZFGC is generally supportive of the proposal to amend Standard 1.2.3 in order to exempt four products (soybean oil, soybean derivatives – tocopherols and phytosterols, distilled alcohol from wheat or whey and glucose syrup from wheat starch) from mandatory labelling requirements for allergens. We welcome the initiative to align New Zealand and Australian requirements with those in Europe and North America. However, we note that the proposals concerning the threshold exemption level for corn [sic] glucose syrup [assumed to mean derived from wheat] of 10 mg/kg (ppm) provide no greater reduction in risk for consumers than 20 mg/kg, would be very costly for no consumer gain, are not aligned with international standards and therefore create a trade barrier for imported confectionery. Raised the following concerns in regard to glucose syrup from wheat starch: • there is no differential risk to the consumer for gluten content of 10-20 mg/kg • European Commission regulations for composition and labelling of foods	New Zealand Food & Grocery Council (NZFGC)	Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended variation. This also addresses issues of international harmonisation and reduction of trade barriers.

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suitable for people intolerant to gluten, in which the terms “gluten-free” (not exceeding 20 mg/kg) and “very low gluten” (not exceeding 100 mg/kg**)** are set. It came into force on 1 January 2012 • revised Codex standard for foods for special dietary uses addressed to persons intolerant to gluten (Codex Alimentarius Commission, 2008). “Gluten-free” foods were defined as dietary foods consisting of, or made only from, one or more ingredients that do not contain wheat, rye, barley or oats, and in which the gluten content does not exceed 20 mg/kg of the food as sold or distributed to the consumer • FSANZ proposal of a threshold of 10 mg/kg is to ensure that gluten levels in glucose syrup are as low as technically achievable based on information provided by a single manufacturer in Australia. FSANZ has misinterpreted manufacturing data. Our understanding is that if the mandatory level was set at 10ppm, the manufacturer would need to set a lower threshold as the manufacturing target for compliance purposes. This would be a very costly exercise for no consumer gain and potentially import replacement in the longer term. • Trade barriers will be created if a mandatory exemption level is set at 10ppm • FSANZ uses a single meal consumption of 100 g of confectionery as the high level consumption based on Australian food consumption data for 7-16 year olds which indicates that between 75-91 g of confectionery may be eaten in a children’s birthday party scenario. The 100 g assumes that all confectionery contains glucose syrup. This is demonstrably not the case. The use of glucose syrup in Australia and New Zealand is estimated to be very low (possibly less than 5%) in confectionery and imports of confectionery that may be more likely to contain glucose syrup are estimated to comprise less than 10% of total confectionery consumed in Australia and New Zealand. This would mean that if a high consumer amount of confectionery for children is 100 g, less than 5-10g contains corn [sic] glucose syrup and a level of 100 mg/kg would suffice.		The dietary modelling presents a ‘worst case scenario’ for consumption at a single sitting and uses new industry data for inclusion of glucose syrups in confectionery and ice-creams. The new data for confectionery, filled chocolates and ice-cream indicates a range of 1-70% glucose content, with most confectionery and chocolate at or below 30%; ice-cream at or below 10%. The modelling has also been revised on the basis of this new data provided by industry and to incorporate the 2011-13 Australian Health Survey consumption data and New Zealand consumption data. In a model that aims to estimate an acute dose consumed by a high consumer of confectionery or chocolate at a single sitting or over 24 hours (worse case) the market share of products with wheat based as opposed to corn- or tapioca – based glucose syrup is not relevant.
MPI notes it would be interesting to obtain any data or information on extent of uptake of these exemptions in EU or US (highly refined oils) and whether there has been any monitoring of the effects on reported reactions. For glucose syrup derived from wheat starch, why has a dietary exposure assessment only been based on the Australian population (as 2002 NZ	New Zealand Ministry for Primary Industries (MPI)	FSANZ is unaware of reports on adverse reactions to these highly refined oils. New Zealand data have been included in the revised dietary modelling and taken account of in the conclusions. A high

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National Children's survey is available)? As the 2002 NZ National Children's Survey data is available to use, it may be possible that intakes of confectionery and chocolate are different between Australia and NZ. Questioned why dietary exposure was estimated for children only?		intake of confectionery amongst both adults and children is noted however, we are also aware the New Zealand manufacturer of glucose syrups provides New Zealand industry with 90% of its glucose syrup requirements, and this New Zealand glucose syrup is corn based. FSANZ also understands imported syrups and imported confectionery typically comprise corn or tapioca based syrups.
Infant formula products may require separate consideration, for example, soybean oil could be considered as requiring declaration, given the body weight and consumption of infant formula made with soybean oil as the source of fat. Dietary modelling is suggested for this population group.		No detectable protein in the oil means the risk is minimal for any consumer irrespective of age. Stimulation of the immune system by an allergen is by an absolute amount of protein, ie 1 mg/person not on a bodyweight basis ie. 1 mg/kg bw. Therefore, dietary modelling would not add value in this case.
Although Table 5 in risk assessment noted that consumption of confectionery and chocolate could not be added together, it would be prudent to assume that consumers of chocolate also consume confectionary.		With respect to Table 5 and confectionery and chocolate, the consumption figures reported were high percentile amounts for consumers of that food only. It would therefore be inappropriate to add chocolate and confectionery as we cannot assume high consumers of one are also high consumers of the other, at the same time. To take account of consumption of all products that may contain glucose syrup into account we would need to use mean consumption amounts for the whole population in the calculations, and these would be much lower amounts. Whereas, we were interested in presenting the 'worst case' scenario.
Provided the following comments to questions identified in the CFS: • The FAISAG considered that 1 mg was a NOAEL and wheat allergic patients would be protected if glucose syrups were prepared in accordance with Appendix 2. However, the NZMPI has consulted a NZ allergen specialist who suggested that any levels of wheat protein may elicit a response in a wheat allergic individual. Therefore, MPI suggests further consultation is needed with allergen specialists to resolve this divergence. • MPI suggests that all lines of communication are included to ensure that consumers understand the change. • Voluntary declaration may still be desired by suppliers/manufacturers (e.g. to differentiate soybean oil from palm oil), this may present confusion for		Whilst appreciating there may be divergent views among allergen specialists, FSANZ accepts the advice of its expert advisory panels, which in this case comprised leading allergen specialists from across Australia and New Zealand. The Food Allergy and Intolerance Scientific Advisory Group was established in 2009 to assist FSANZ in managing allergens in foods and across a number of projects. For reasons of consistency and benefiting from their experience in the broader allergen related work the same group was used to advise FSANZ in respect of P1031. The extreme sensitivity of some allergen sufferers is recognised, and in

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consumers. Suggest advice to consumers that voluntary declaration is still permissible is covered in communication materials. • Cost-benefit analysis: A cost should be added that relates to the risk associated with ingredients that do not comply with maximum level of protein/production method. • An ML lower than 10 mg/kg for glucose syrup could be considered or FSANZ should comment on the clinical significance for allergy sufferers of 1 mg or more ingestion of wheat protein. Fully refined soybean: In SD1 section 1.11 summary, is there an error in 4th para: The figure 0.005 appears incorrect? Propose a maximum protein/kg oil-more effective for enforcement. There should be discussion as to why there is no information or analytical data on glucose syrup manufactured in NZ.		this context it is acknowledged that 100% safety cannot be assured for allergen sufferers. However this holds true for the food supply generally. Costs associated with non-compliance already exist for the status quo. The figure of 0.005 mg in respect of soybean protein from one meal with soybean oil is a typographical error, it should read 0.05 mg. A maximum level of protein/ kg oil was considered as a risk management approach however, on further consideration this was found to be impractical for analytical and enforcement purposes due to the difficulties of obtaining such measurements easily and reliably, especially within the context of a fat-based food matrix. It was also felt not to be necessary due to the universality and effectiveness of full refinement of such oils through the N/RBD process. Information was received from a late submission from New Zealand Starch Ltd on the absence of gluten in New Zealand produced glucose syrups which are not sourced from wheat but corn.
New Zealand Starch Ltd is a commercial manufacturer of corn-based glucose syrups and starches, and is the predominant supplier for New Zealand with substantial sales in Australia. Based on the CFS, levels below detection level for gluten (in glucose syrups) would present 'no risk' to wheat allergic consumers, whereas 10-20 mg/kg is likely to present 'negligible risk'. Based on this it would seem that some individuals would be at risk and therefore should be considered important.	New Zealand Starch Ltd (LATE COMMENT)	The risk assessment has concluded that 10-20ppm gluten presents negligible risk to the majority of wheat sensitive individuals, and as such provides an opportunity for a wider range of food choice for this majority. It is acknowledged that levels below detection would present less risk however, other risk management strategies (as discussed in section 2.3.1.2) are employed by individuals who may experience allergic reactions at such low doses. A lower limit would

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Products containing wheat gluten or residues thereof, that are labelled as 'gluten-free' would cause confusion. Consumers must be allowed to decide by having wheat declared on the label. The proposed product would increase risk to consumers when there is a viable [gluten free] product already available. New Zealand Starch Ltd Support the application of a consistent level of detection for all products and therefore would not support relaxation of the currently accepted and workable standards in Australasia.		also compromise food choice, and imposes trade restrictions and costs on manufacturers unnecessarily. Expert advice to FSANZ is that high risk individuals do not rely on labelling for risk managing their condition. Products containing wheat gluten at above levels of detection will not be able to declare themselves as 'gluten-free. This is the status quo and is not changed under this Proposal therefore, there is no reason to assume increased confusion for consumers.
Overall the proposed exemptions present a net benefit. Costs in relabelling products will naturally be experienced, however, Sanitarium recognises that these label changes can take place gradually as the proposed variation is an exemption rather than a prohibition. Other costs that may be experienced initially, relate to responding to consumer questions about why changes have been made to our labels. Benefits to industry as discussed include reducing the length of ingredient lists and allergen summary statements on packaging, therefore freeing up space on food labels. The proposed exemptions would also increase alternative ingredient choices for food manufacturers without the need or added cost for relabelling. Further benefits also include alignment with international regulations and increasing the food choices available to allergenic consumers. Sanitarium supports the Proposal to allow for specific exemptions from allergen declarations for glucose syrups from wheat starch, fully refined soybean oil, soybean derivatives (tocopherols and phytosterols) and distilled alcohol from wheat or whey. Sanitarium notes that P1031 is for the specific food ingredients mentioned above, however we would welcome this Proposal being expanded to include other suitable materials, thereby further increasing food choices for allergenic consumers and relieving industry of the labelling burden for materials which through production methods removes or reduces allergenic proteins. Of particular interest would be the inclusion of maltodextrin derived from wheat starch which is already included in European Union regulations.	Sanitarium	The exemptions proposed for consideration were arrived at following extensive consultation with industry, consideration of available evidence and practical implications. FSANZ acknowledges the list is not exhaustive. Other foods/ ingredients may warrant consideration in due course and the application pathway remains open to stakeholders wishing to pursue any such foods or

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		ingredients.
Support	Spirits New Zealand	Noted
TATA support the allergen labelling exemptions proposed by FSANZ. Two EFSA documents (Opinion of scientific panel) to substantiate this exemption were submitted.	TATA Global Beverages Limited	Noted
Agree that the products, and their methods of production as described, would be of negligible risk to consumers sensitive to the allergenic foods from which they are prepared. Raised concerns about the proposed maximum level of gluten permitted in glucose syrups derived from wheat. Setting the level at 10 mg/kg would put Australia and New Zealand out of step with the US and EU where gluten-free claims may be made where the level is less than 20 mg/kg. Are aware of industry intentions to make an application to FSANZ to seek alignment with the US and EU (and Codex) on gluten-free claims. In this light it would be prudent to either: • Set the upper limit for gluten in wheat-derived glucose syrup at 20 mg/kg; or • Not set an upper limit and be more explicit about the required production criteria. Support the rationale for exempting certain products from allergen labelling, and alignment with international regulation. As work on thresholds progresses we can expect to see more products become eligible for exemption consideration. The EU currently exempts distillates from cereals, whey and nuts. The risk assessment carried out by FSANZ for wheat and whey under this Proposal could be equally applied to other cereals and nuts, as allergenic proteins are not volatile and will not, under GMP, carry over into distillate. On this basis, the department's request that FSANZ also considers excluding distillates from other cereals and nuts from allergen labelling requirements.	Victorian Department of Health and Human Services, and the Victorian Department of Economic Development, Jobs, Transport and Resources	Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended variation. The exemptions proposed for consideration were arrived at following extensive consultation with industry, consideration of available evidence and practical implications. FSANZ acknowledges the list is not exhaustive. Other foods/ ingredients may warrant consideration in due course and the application pathway remains open to stakeholders wishing to pursue any such foods or ingredients.
In general, Unilever supports the FSANZ Proposal which is to introduce allergen labelling exemptions to the Food Standards Code, where the evidence base supports negligible risk to allergic consumers, to bring about international consistency for allergen labelling. In summary, we fully support the risk assessment management recommendations for the 3 allergen exemptions below which are evidence	Unilever	

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based and consistent with EU exemptions: • N/RBD soybean oil, • Phytosterols & tocopherols • Alcohol distillates. In regard to glucose syrup from wheat, we support the proposed allergen exemptions, however as per the risk assessment and subsequent proposal outlined by FSANZ, we do not support the proposed limit of 10 mg/kg level put forward whereby exemption will be permitted. Submission covered the risk assessment outcomes for glucose syrup from wheat starch. We strongly recommend FSANZ consider a similar situation for Australia and New Zealand and remove the limit of 10ppm and instead work towards GMP or provide a limit for 20 mg/kg. 1. There is a similar level of risk for 10-20 mg/kg; 2. The local manufacturer does NOT support the 10 mg/kg level and being required to operate at this level will impose significant extra cost, where there is not a demonstrated benefit; 3. This is not consistent with the EU labelling exemption in practice – a region that relies heavily on wheat-based glucose syrup similar to Australia and New Zealand.		Increasing the proposed limit of residual gluten in glucose syrups from 10 to 20 mg/kg has been addressed in the amended variation. This will bring provisions in line with Europe. Serious consideration was given to using GMP or a code of practice as a risk management strategy however, for various reasons this was not seen as practical for industry or enforcement.