17 March 2016
[07–16]

Approval report – Proposal P1031

Allergen Labelling Exemptions

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to allow for specific exemptions from allergen declarations for glucose syrups from wheat starch, fully refined soy oil, soy derivatives (tocopherols and phytosterols), and distilled alcohol from wheat or whey.

On 12 August 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 29 submissions.

FSANZ approved the draft variation on 3 March 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 16 March 2016.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/P1031Allergenlabellingexemptions.aspx

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Executive summary

The *Australia New Zealand Food Standards Code* (the Code) requires the presence in a food for sale of a food or substance derived from certain allergenic sources, specified in Standard 1.2.3, to be declared (with some limited exemptions), either on the label or, for foods not required to carry a label, in other ways as prescribed in the Code.

FSANZ is proposing to exempt certain foods and ingredients derived from the respective 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.

FSANZ, together with a working group from the Australian Food and Grocery Council's Allergen Bureau, identified four products for consideration for exemption 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
- glucose syrup derived from wheat starch
- alcohol distillate made from wheat or whey.

FSANZ conducted a risk assessment and concluded that soybean oil that has been fully refined i.e. degummed, neutralised, bleached and deodorised (N/RBD) presents negligible risk to soybean allergic consumers. Tocopherols and phytosterols are removed in the last stage of refining of soybean oil and therefore also present negligible risk. Similarly, alcohol distilled from wheat or whey presents negligible risk to susceptible individuals. The risk assessment concluded that based on available evidence, wheat-derived glucose syrup that has been processed and containing 10–20 mg gluten/kg glucose syrup is considered safe for consumption by sensitive wheat allergic individuals. FSANZ consulted with an expert group of allergy specialists in Australia and New Zealand on the risk assessment for this Proposal.

Risk management measures were subsequently developed in order to implement the proposed exemptions, resulting in a draft variation to the Code.

Two options were considered as part of the assessment of this Proposal:

- preparing a draft variation to Standard 1.2.3 and consequential amendments (Option 1)
- abandoning the Proposal (Option 2).

A limited impact analysis of the cost and benefits was prepared which indicated Option 1 provided the greatest net benefit through increased food choice for allergic consumers and increased trade opportunity and competitiveness for industry. If the Australia and New Zealand Forum on Food Regulation has no objection to the variation, the current mandatory allergen declarations for the products under consideration would no longer be required.

The Proposal was consulted on and received 28 submissions and two late comments at the public call for submissions. Overwhelmingly, submitters supported the Proposal. Some concerns were raised about details of the proposed risk management measures. Questions were also raised about whether there were safety and enforcement issues in respect of the foods and ingredients being considered. FSANZ subsequently sought further data and commentary from key submitters about these concerns.

As a result the proposed variation in respect of glucose syrups derived from wheat was amended. At the call for submissions, the proposed risk management approach for glucose syrups derived from wheat was to set a regulatory limit for allergen declaration exemption at less than or equal to 10 mg/kg. Submissions clearly indicated this approach was not widely supported. A level of 20 mg/kg was seen as preferable (by the majority) in order to ensure 100% compliance with current technical achievability and international harmonisation. One stakeholder suggested a lower level of equal to or less than 5 mg/kg.

The exemptions will widen the range of products available to allergic consumers and benefit industry. These products are exempted by the European Union (EU) based on specified production methods, and either are, or may be, eligible for exemption in the United States of America (USA) and Canada based on absence of allergenic protein or scientific demonstration that they do not cause an allergic response.

FSANZ therefore amended and then approved the variations to Standard 1.2.3 that were the subject of the call for submissions.

1 Introduction

1.1 The Proposal

FSANZ is proposing to exempt certain foods and ingredients derived from allergenic foods from mandatory declaration of allergens where available evidence indicates production methods used remove or reduce allergenic proteins to levels that are of negligible risk to allergic consumers.

1.2 The current Standard

All references to the Code in this Report and related Supporting Documents (SDs) are to the revised Code which took effect and replaced the current Code on 1 March 2016.

Section 4 of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations, for the *Australia New Zealand Food Standards Code* (Code) requires the presence of a food or substance wholly or partially derived from the allergenic sources listed in that standard to be declared (with some exemptions). Allergenic sources listed in that Standard include cereals containing gluten, crustacea, egg, fish, milk, peanuts, sesame seeds, soybeans and tree nuts. For products that are not required to bear a label, e.g. those that are served direct to consumers or unpackaged for other reasons, declarations are required to be made on or in connection with the food, or provided to the purchaser upon request (refer to section 9 of Standard 1.2.1 – Requirements to have labels or otherwise provide information in the Code) or for food sold to a caterer, provided on a label or in accompanying documentation (refer to Standard 1.2.1, sections 15 and 16 respectively). For the purposes of this document, general discussion about products being labelled should also be taken to include those products that are not required to bear a label.

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 present 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.

Standard 2.9.5 and Schedule 10 in the Code also provide for allergen declarations. Standard 2.9.5 – Food for special medical purposes addresses allergen declaration requirements by cross-referencing Standard 1.2.3. Schedule 10 – Generic names of ingredients and conditions for their use requires in the context of otherwise generically labelled fats and oils that, where the source is peanut, soybean or sesame, the specific source name must be declared. The requirement pertaining to soybean oils is relevant to this Proposal.

1.3 Reasons for preparing Proposal

There is evidence that some products that must be declared under Standard 1.2.3 do not pose a risk to allergic consumers. As a consequence, food choice for allergic consumers is unnecessarily restrictive and the current labelling requirements are unnecessarily onerous for industry and regulatory agencies. Additionally, Australian and New Zealand industries face market limitations and trade issues that hamper international competiveness, because of exemptions to allergen declarations that are already in place (especially in Europe and North America).

1.4 Procedure for assessment

The Proposal was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Twenty-eight submissions and two late comments were received in response to a call for submissions for this Proposal. Issues raised are identified here, and responses by FSANZ provided in the risk assessment and risk management sections below, sections 2.2 and 2.3 respectively. A table containing further detail from submitters and responses from FSANZ is provided as SD3.

Stakeholders raised issues relating to consumer safety, technical achievability, impacts on market competitiveness and enforceability.

Overall, submitters supported the proposed exemptions 'in principle' however, a number of comments were received about risk management, especially for glucose syrups derived from wheat.

The proposed approaches for allergen labelling exemptions for fully refined soybean oil, soybean derivatives (tocopherols and phytosterols), and distilled alcohol from wheat or whey were generally supported. There were some questions about the reliability of production methods to ensure the products are suitably and effectively refined to remove allergenic proteins.

2.1.1 Glucose syrups from wheat

The issue of most concern was the proposed regulatory measure for glucose syrups derived from wheat using 10 mg/kg gluten as the upper limit regulatory parameter for exemption. This approach was based on what FSANZ understood at the time to be practically achievable. The overwhelming response from submitters was 10 mg/kg was not practical and that 20 mg/kg would be more appropriate – based primarily on technical achievability, international harmonisation, costs of compliance (arising for the proposed '10 mg/kg' limit), and on the risk assessment describing no net benefit in safety between 10 and 20 mg/kg gluten protein.

The safety aspects were questioned by some submitters interested in knowing the clinical significance for allergy sufferers of 20 mg/kg gluten or more, and the likelihood of children ingesting this maximum amount on one occasion e.g., of confectionery. Some questions were raised about the dietary modelling, particularly in respect of data used for glucose syrups in confectionery. FSANZ was asked to further consider dietary intakes for children and using New Zealand data. Comments were also received that the dietary modelling was overly conservative and thereby overestimated the respective dietary intakes. FSANZ was also asked to consider New Zealand production of glucose syrups.

A further concern raised by a number of submitters was the affect this Proposal would have on gluten-free labelling. There appeared to be a common misconception that allowing for (wheat) allergen declaration exemptions would also be allowing for gluten-free labelling on wheat-containing products. In some cases, this also related to the suggestion (by submitters) that 20 mg/kg gluten be used to harmonise with international approaches to gluten-free labelling (based on the Codex Alimentarius approach).

The dietary modelling based on various assumptions was queried by some sectors of industry, particularly the confectionery sector in respect of our calculations based on 50% glucose content and consumption of 100 g of confectionery in one sitting. They claimed this is not supported by industry data, which reflect lower glucose contents. Along with other considerations, it was felt that whilst achievable, the results of the dietary modelling present a highly unlikely and overly conservative outcome. It was also noted that wheat-based syrups may be replaced with corn or tapioca (i.e. gluten free) syrups depending on sourcing and supplies thereby, further reducing exposure to wheat.

At the call for submissions, the proposed risk management approach for glucose syrups derived from wheat was to set a regulatory limit for allergen declaration exemption at equal to or less than 10 mg/kg. Submissions clearly indicated this approach was not supported nor seen as consistently achievable by industry. This was subsequently verified by data submitted after the CFS. A level of 20 mg/kg was proposed as preferable in order to ensure 100% compliance with current technical achievability, and consistency with European practice.

2.1.2 Soybean oils and soybean oil distillates

The proposed exemptions for fully refined soybean oils and soybean oil distillates in the form of tocopherols and phytosterols were generally well supported. Concerns raised were predominantly around standardisation and efficacy of production methods, and associated safety and enforcement aspects.

2.1.3 Alcohol distillates from wheat and whey

The proposed exemptions for alcohol distillates from wheat and whey were widely supported and largely without comment.

2.2 Risk assessment

Foods are mainly composed of proteins, carbohydrates and lipids. For allergenic foods, the risk to allergic consumers is almost always associated with proteins. The risk to allergic consumers is a function of the likelihood of an allergic reaction occurring at the dose of allergenic food consumed and the severity of reaction. The dose depends on the concentration of the residual protein in the product and amount consumed. Various products derived from allergenic foods contain little or no protein as a result of chemical and/ or physical processes which separate and remove the proteins. Although not all proteins in a food allergen are allergenic, minimising the total protein content in products derived from the allergenic sources would minimise the risk to allergic consumers.

The risk assessment in this report relates to four products derived from allergenic foods. The products are: soybean oil that has undergone a complete refining treatment, i.e. degummed, neutralised, bleached and deodorised (N/RBD) soybean oil; tocopherols and phytosterols derived from the deodoriser distillate of N/RBD soybean oil; glucose syrup from wheat starch; and alcohol distilled from wheat and whey.

FSANZ considered available evidence from published and unpublished oral challenges with each product in allergic patients. Analytical data on residual protein levels in samples from each of the products were also considered. The acute dietary exposure was estimated from the amount of each allergen present in food and food consumption data from Australian national nutrition survey data. The assessment also considered information on the processing steps which account for reducing protein content in the final product. Where available, data on allergen thresholds were incorporated into the assessment. Thresholds are the highest amount of allergenic food that can be consumed in a single meal without causing an allergic reaction.

FSANZ undertook two consultations with the Food Allergy and Intolerance Advisory Group (FAISAG) to gain input from allergy clinicians in Australia and New Zealand. In particular, FSANZ sought input on suitable risk assessment terminology to describe the level of risk and to determine whether conclusions can be drawn from the available evidence.

The risk assessment concluded that N/RBD soybean oil presents negligible risk to soybean allergic consumers. The conclusion is based on the negative results of clinical studies of dose escalation oral challenges, the analytical data showing extremely low/ undetectable protein content in N/RBD soybean oil, and the limited dietary exposure to soybean oil in one meal. With regards to the effect of the processing steps on protein content, the data indicate that the bulk of soybean protein is removed during degumming, the first step in the oil production process. Residual impurities, including proteins, are reduced further by the neutralising step using alkali, and the bleaching step using activated clay or silica.

Finally, the soybean oil is deodorised to remove volatile substances such as odours and off-flavours. The full process results in N/RBD soybean oil virtually devoid of any protein. Analytical data of N/RBD soybean oils sourced from different countries indicate that soybean protein levels are consistently <1 mg/kg. Cold pressed soybean oil is not included in this assessment as the protein profile of cold-pressed soybean oil is very similar to that of soybean flour.

Phytosterols and tocopherols, highly processed products derived from the deodoriser distillate of N/RBD soybean oil were considered. The distillate is generated in the final step of N/RBD soybean oil production. Analytical data confirmed that protein was not detected in the distillate and tocopherols or phytosterols are also unlikely to contain detectable protein. This is not surprising since soybean protein is removed in the production of N/RBD soybean oil. It also follows then that, like N/RBD soybean oil, tocopherols and phytosterols present negligible risk to soybean protein allergic consumers.

The available clinical data suggests that acute dietary exposure (a single eating occasion) to no more than 1 mg of wheat protein is unlikely to provoke an IgE-mediated immunological response in the majority of wheat sensitive individuals. Consumption data indicates that the amount of food (confectionery or chocolate) consumed per day for high consumers was between 52-100 g for Australian 2-4 year olds; between 100-183 g/day for 5-14 year olds in Australia and between 100-232 g/day for 5-14 year olds in New Zealand. Confectionery products contain glucose syrup in various amounts between 1-70% of the final product, however not all the glucose syrup is derived from wheat, particularly in New Zealand where the sole manufacturer meets 90% of its glucose syrup requirements and this glucose syrup is corn-based.

Minimising gluten in all glucose syrup samples to as low as technically and practically achievable 100% of the time (i.e. <20 mg/kg), would mean that dietary exposure for consumers is not likely to exceed 1 mg of wheat protein on a single occasion. 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 Appendix 2 of SD1 would present negligible risk to the majority of wheat allergic individuals; such syrups would also be suitable for those with coeliac disease.

FSANZ has recently sought information from Europe on any reports of adverse reactions to wheat based syrups in foods where wheat based syrups have been subject to industry-based compliance processes to achieve gluten levels of <20 mg/kg since 2007. At the time of preparing this report, we are advised that there have been no reports.

Another category of products considered in this risk assessment were alcohol distillates from wheat and whey. The available analytical data confirm that protein is undetectable (i.e. <1 mg/kg) in distilled ethanol from whey and wheat. In a properly controlled distillation process, non-volatile substances such as lactose and proteins from wheat and whey are not found in the distillate. On this basis, products made from distilled alcohol, such as vinegar would not contain protein. The risk assessment concluded that alcohol distilled from wheat and whey, including vinegar derived from distilled alcohol, presents a negligible risk to susceptible individuals.

The full Risk Assessment report is provided as SD1.

2.3 Risk management

The risk assessment identifies three products and two alcohol distillates from allergenic sources where the levels of protein are so low as to present negligible risks to the majority of susceptible individuals. Where this is so, the need to provide allergen declarations on product labels or as otherwise required may be overly restrictive. This Proposal was prepared to consider exempting from mandatory declaration the identified products, and any products further derived from those where the processes undergone are not likely to increase the allergenicity of the original product.

The protection of public health and safety is FSANZ's primary objective. The risk assessment noted the conditions under which allergenic consumers would be at negligible risk from foods where the allergenic protein had been removed. However, within this context, the extreme sensitivity of some allergen suffers is recognised. It is acknowledged that 100% safety cannot be assured for allergen sufferers 100% of the time and this holds true for the food supply generally.

The ingredient listing continues to provide ingredient information, as per the requirements of Standard 1.2.4. Whilst under the circumstances addressed by this proposal certain ingredients that are currently required to declare allergenic sources will no longer need to do so, that is because safety assessment deems it unnecessary. It is understood that highly sensitive allergic consumers employ other precautionary measures in food choice, such as relying on known products and suppliers, avoiding highly processed foods where all contents may not be known, and preparing foods from primary ingredients in their own homes; rather than relying solely on label information.

The basis of exemption varies according to product. For soybean oils and soybean-derived tocopherols and phytosterols, and whey or wheat distillates, the processing methods used means the remaining product is virtually devoid of protein.

2.3.1 Glucose syrups from wheat

Upper residual protein limits are proposed for glucose syrups derived from wheat where processes are designed to remove protein but small amounts of protein may still remain. In this case, the available clinical and scientific evidence indicates that residual protein levels are considered to be within limits safe for consumption by the majority of allergic individuals. The approach of setting limits for purposes of declaration exemptions is not dissimilar to that currently adopted for sulphites, where clinical susceptibility is taken into account in order to arrive at an acceptable level for the purposes of declaration on the label.

FSANZ has undertaken further, and extensive, consultation with glucose syrup producers and their customers (i.e. those using glucose syrups as ingredients in manufactured foods). As a result of these investigations FSANZ has concluded that requiring these syrups to meet equal to or less than 10 mg/kg gluten was neither feasible nor cost effective.

Furthermore, as safety for wheat sensitive individuals and sufferers of coeliac disease, based on 'worst case' scenario dietary consumption patterns, has been assessed as being adequately met by glucose syrups within the range of 10–20 mg/kg gluten, then the more cost effective and technically achievable limit of < 20 mg/kg was seen as acceptable. 20 mg/kg also aligns with industry-based compliance processes in Europe, and accepted by other countries such as those in Asia. Therefore, this approach facilitates harmonisation and avoids unnecessary barriers to trade. Notwithstanding this, the FAISAG has made it clear that industry should strive for the lowest possible residual gluten levels in glucose syrups, and in the interests of a safe food supply, it is incumbent on industry to take this fully into account.

Reference to New Zealand production of glucose syrups had not been included in the call for submissions because New Zealand's primary supplier of glucose syrups derives its syrups from corn rather than wheat; as such, New Zealand-produced syrups do not contain gluten or wheat protein. While some wheat-derived syrups may be imported into New Zealand, FSANZ is advised the majority, including products containing them, are derived from corn or tapioca.

FSANZ has been advised by producers and importers of glucose syrups that maintaining a limit in Australia and New Zealand that is different from Europe would result in considerable cost for imported finished products containing glucose syrup, compound ingredients and glucose syrup, and consequently, could adversely affect the competitiveness of Australian industry. Stakeholders were able to describe the effects on the supply chain of different limits (e.g. from re-testing and additional quality control assurance requirements) and quantified costs were provided for the effects on domestic production.

2.3.1.1 Technical considerations

On the basis of submitter comments FSANZ sought further advice about the production methods of the foods/ingredients in question to ensure our previous understandings were correct. Prior to the call for submissions, we were advised that 10 mg/kg residual gluten in glucose syrups was achievable 100% of the time. The previous information was qualified in submissions and subsequent consultations by noting those data were derived from a limited sample, and subsequent increases in production volume, processing factors (e.g. 're-generation' and changes of filters), and factors such as seasonal variability (e.g. sources of wheat, grain gluten levels). This means that whilst most gluten levels in resulting syrups will be relatively low, they may vary more widely (between the analytical method limit of determination and 20 mg/kg) than previously advised.

More recent technical data informs us that, whilst most product would be below 10 mg/kg, currently the technically achievable levels of gluten in glucose syrups derived from wheat 100% of the time is <20 mg/kg and to change production systems such that 100% can be manufactured to <10 mg/kg will cost many millions of dollars, both in start-up and ongoing costs. FSANZ has been provided with data showing that 90% of batch samples taken daily over the past ten months (March 2015–January 2016) had a gluten content of <10 mg/kg, and 10% were somewhere between 10 and 20 mg/kg. Beyond levels of 13–15 mg/kg the syrup is most likely to be rejected regardless due to quality parameters such as colour break-through and tendency to foam.

2.3.1.2 Safety

Gluten is a major constituent of wheat protein (approx. 75%) and as such, analysis for gluten serves as a useful marker for residual protein. The risk assessment for wheat-derived glucose syrups remains as previously determined by the FAISAG who were asked to consider specific questions pertaining to their level of confidence in the safety for wheat allergic consumers of dietary exposure to 1 mg of wheat protein from glucose syrup derived from wheat in any one eating occasion.

In consideration of consumption data for high consumers (97.5 percentile) of products containing glucose syrup, the FAISAG concluded that the majority of wheat allergic patients are likely to be protected if glucose syrups are prepared in manner similar to that in Europe. ELISA kits have shown that the residual gluten content in these glucose syrups is usually lower than the limit of detection (<3 mg/kg). However, due to inherent uncertainties in the literature, the FAISAG concluded that 1 mg of wheat protein is a reasonable estimate of safety, and that industry should aim to achieve levels that are 'as low as technically achievable'. The FAISAG agreed that 1 mg of wheat protein from glucose syrup derived from wheat in any one eating occasion could be used to guide the proposed upper limit of gluten in glucose syrup; that this would protect the *majority* of wheat allergic consumers, and present *negligible risk* to patients with Coeliac Disease. It was acknowledged that 100% safety cannot be assured (in this or most other food allergy cases).

FSANZ stated in the call for submissions Risk Assessment (refer SD1) that 10-20 mg/kg gluten is *likely to present a negligible risk to the majority of wheat allergic individuals.* However, no 'safety' differential was quantifiable for 10 vs 20 mg/kg. Industry stakeholders told FSANZ the extra burden of imposing 10 mg/kg rather than 20 mg/kg is not justified because the costs of meeting 10 mg/kg 100% of the time is much higher than for 20 mg/kg. FSANZ sought further information on the technical difficulties and costs imposed in meeting 10 mg/kg and agree these are significant. With respect to 'safety', FSANZ sought information from Europe on reports of adverse reactions to wheat-based syrups in foods, where wheat-based syrups have been subject to industry-based compliance processes to achieve gluten levels of <20 mg/kg since 2007. FSANZ has been advised, to date, there have been no such reports of any adverse effects from compliant syrups.

The products under consideration have been assessed as safe for the majority of allergic individuals due to the absence or minimal presence of allergenic proteins. As stated earlier, safety for consumers is the primary concern of FSANZ, but FSANZ equally recognises that safety cannot be assured for 100% of consumers 100% of the time. This is also recognised and accepted by consumer representative organisations that educate members to be medically prepared for an adverse event at all times. While food labels can be seen as a useful part of a broader suite of risk management strategies for facilitating food choice, they should not be used as the sole source of information for matters as serious as food allergies. Food labels are required to provide ingredient listings however, highly sensitive individuals would more typically prepare their foods from basic ingredients so they are fully aware of the content and preparation processes. Contact details for suppliers of food products are required on labels and in cases where processed foods may need to be purchased, allergic consumers may contact companies directly and stay loyal to brands they consider 'safe'. Even though certain foods may not be problematic the vast majority of the time, unforeseen allergic responses can still happen unexpectedly due to a number of factors including both inherent and external variability in individual sensitivities. Moreover, food allergic individuals prescribed emergency medication are routinely advised they must always be prepared for unforeseen events.

2.3.1.3 Labelling – gluten

Proposal P1031 has no impact on, nor any intention to address, gluten-free labelling. The current provision of 'gluten-free' is applicable to only those foods/ingredients containing no detectable gluten. Therefore, glucose syrups where the level of gluten is above the level of detection will remain ineligible to claim gluten-free status.

2.3.2 Soybean oils and soybean oil derivatives

Only fully refined soybean oils will qualify for exemption, where fully (or chemically) refined refers to a process that is universally understood, and generally referred to as N/RBD (degummed, neutralised, bleached and deodorised).

Through this process, the resulting oil is virtually devoid of protein and FSANZ is unaware of any reported allergic responses to such refined oils. However, cold pressed soybean oils are not refined in this way, and as such, do not qualify for exemption.

The exemption for soybean oils also has implications for Schedule 10 of the Code whereby, fats and oils that may otherwise be generically labelled, must, where the source is *peanut, soybean or sesame*, declare the specific source name. The source declaration as soy/ soybean will no longer be required for fully refined soybean oils, and therefore a consequential amendment has been made to Schedule 10.

The soybean oil distillates in the form of tocopherols and phytosterols also qualify for exemption by virtue of the distillation process resulting in substances virtually devoid of protein.

2.3.3 Alcohol distillates from wheat and whey

Alcohol distillates from wheat and whey are highly refined through the distillation process that removes virtually all protein. Wheat distillates may be used in products such as whisky, and whey distillates are used, for example, in the production of various vinegars.

2.3.4 Labelling aspects

The labelling implications of Proposal P1031 are that the respective allergen (i.e. soy, wheat or milk) would no longer be subject to mandatory labelling declarations for the foods/ ingredients under consideration. Allergen declarations can still be made voluntarily, and all other labelling requirements, such as ingredient listing, still apply.

With respect to the wheat-derived glucose syrups, there appears to have been confusion amongst submitters between mandatory allergen declarations and gluten-related labelling. Whilst Proposal P1031 uses gluten protein as a (pragmatic) parameter for regulatory purposes, P1031 makes no variations to gluten-related labelling provisions. The current provisions for gluten declarations as per Standard 1.2.7 - nutrition health and related claims, including gluten-free (i.e. no detectable gluten) or low gluten (≤20 mg/kg gluten) claims, remain.

This Proposal is separate from other allergen labelling matters currently being considered by FSANZ and is not dependent on the others for progression, even though they have ‘allergens’ in common. As this specific project (allergen exemptions) is about removing information from labels, its implementation can occur at any time that suits individual manufacturers and suppliers.

2.3.5 International practice on allergen labelling

The FSANZ Act requires FSANZ to have regard to, among other things, international harmonisation of foods standards and to the desirability of an efficient and competitive food industry, taking account of both domestic and international trade. International discussions on food allergens started in the mid-1990s and led to the development of standards first by the Codex Alimentarius (Codex) in 1999, followed by a number of countries including Australia and New Zealand (2000), EU (2003), USA (2004), and Canada (2011). Although there is a common core list of allergenic foods in these countries, the regulatory approaches taken vary, including whether or not certain products are exempt and if so on what basis. For example, in the USA and Canada products may be exempted based on scientifically demonstrated safety for allergic individuals, or absence of allergenic protein as the case may be, and in the EU exemptions are considered based on evidence products do not cause adverse reactions.

With regard to the products being considered in this Proposal, the source products, i.e. dairy milk, soybean and wheat, are also identified as allergens by Codex and by many other countries that address allergen labelling e.g. EU, USA, Canada, China, Hong Kong, Japan, Korea and Mexico (Gendel, 2012[1]). Some countries and Codex do not provide exemptions. The products considered here are also exempted by the EU (as part of a list of 13 exemptions) and, based on absence of protein, may be eligible for exemption from the USA and Canada. The USA specifically identifies the exemption of highly refined oils derived from their major food allergens, whereas Canadian requirements only apply to foods containing the component responsible for adverse reactions (i.e. protein). The USA and the EU also provide ways for suppliers to request further exemptions from labelling requirements. For example, under the US Food Allergen and Labelling Consumer Protection Act of 2004 (FALCPA), manufacturers may obtain an exemption by submitting a petition that provides scientific information demonstrating that an ingredient derived from a major food allergen does not cause an allergic response that poses a risk to human health; or submitting a notification providing scientific information demonstrating that the ingredient does not contain allergenic protein.

Supporting Document 2 (SD2) provides a table outlining labelling exemptions for Australia and New Zealand, the EU, USA and Canada.

2.3.6 Impact analysis

FSANZ conducted a limited cost benefit analysis for this Proposal. That analysis found that there are benefits to consumers, the food industry and little impact on government. Consumers with allergies benefit from having a greater range of foods to choose from, without safety being compromised. Manufacturers of some ingredients (such as glucose syrup derived from wheat) no longer face a disadvantage compared to manufacturers of similar ingredients manufactured from non-allergenic sources. Manufacturers no longer have to devote label space to declaring the presence of ingredients that are actually safe for the vast majority of consumers to eat. Manufacturers have more freedom to switch between similar ingredients without re-labelling (such as suitable soybean oils). Harmonisation with international regulations facilitates trade, increases competitiveness and could reduce the need for companies selling to multiple markets to produce different labels. For international markets to cater to unique Australian and New Zealand needs is not economically feasible.

FSANZ concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Proposal outweighed the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option was to prepare draft variations to the Code to exempt certain ingredients derived from allergenic sources from mandatory labelling.

2.3.7 Risk management conclusion

FSANZ concludes that there is a net benefit from exempting certain ingredients derived from allergenic sources from mandatory labelling. These will either be exempted on the basis of production method or by setting maximum levels of the respective allergens (based on protein levels). The risk management approach was to specify that production methods (i.e. distillation or the refining of soybean oil) are adequate to manage the risk for soybean oil, phytosterols and tocopherols and alcohol distilled from wheat and whey and vinegar distilled from these products.

[1] Gendel SM (2012) Comparison of international food allergen labeling regulations. Regulatory Toxicology and Pharmacology 63:279-285.

In the case of glucose syrup, the appropriate risk management measure was to set a maximum level for gluten which may be present to qualify for an exemption. Other labelling requirements were also considered and a consequential amendment was required to remove the requirement for the specific source name for oils derived from soybean to be given when the oil meets the conditions for the exemptions under standard 1.2.3.

As evaluated above, the risk management measures took into account public health and safety, technical aspects including production methods, trade and cost implications and enforceability. FSANZ has assessed that the approaches protect health and safety, whilst also meeting the needs of an efficient and competitive environment for manufacturers, importers and exporters.

2.4 Decision

Having taken into account the risk assessment and concluding that certain foods which currently require declaration can be exempted from these requirements, FSANZ has made a variation to the Code.

The draft variation as proposed following assessment was approved with amendments and is Attachment A. The variation takes effect on gazettal. The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C.

2.5 Risk communication

Consultation is a key part of FSANZ's standards development process. FSANZ prepared a communication strategy for this Proposal, which included targeted communication with key stakeholders and the preparation of information for the broader community. FSANZ is also working with key consumer groups and other interested stakeholders on ensuring consumers (in particular) are informed about the proposed changes. A number of submitters including consumer, public health and industry representatives, have offered to assist in communicating changes to consumers, and a communication strategy that draws on this assistance will be implemented post approval of the variation and before gazettal.

All calls for submissions were notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties were notified about the availability of reports for public comment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. A six week consultation period was held for this Proposal and 28 submissions were received. Two further representations were received as late submissions. FSANZ undertook further targeted consultation with a number of submitters to obtain more data, clarify comments, and explore issues raised.

Every submission on the proposal was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ also acknowledges the expertise of members of the FAISAG.

2.6 FSANZ Act assessment requirements

2.6.1 Section 59

2.6.1.1 Cost benefit analysis

FSANZ has considered the costs and benefits that would arise from this Proposal and concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure (refer section 2.3.6).

The Office of Best Practice Regulation (OBPR) in an email of 19 June 2014 (OBPR ID 17177) advised FSANZ that the proposed amendments are likely to have only a minor regulatory impact. This is because the Proposal will offer a minor reduction in regulatory burden for food manufacturers/retailers, while not reducing protection for consumers. As such, a COAG Regulation Impact Statement did not need to be prepared for this matter.

2.6.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

2.6.1.3 Any relevant New Zealand standards

The draft variation will apply to joint Australia New Zealand standards.

2.6.1.4 Any other relevant matters

There were no other relevant matters relevant to the decision to approve the exemption of certain ingredients from mandatory allergen labelling.

2.6.2. Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

For the reasons mentioned above (in section 2.2 and SD1), FSANZ is of the view that this Proposal poses minimal risk to public health and safety. The products under consideration have been assessed as safe for the majority of allergic individuals due to the absence or minimal presence of allergenic proteins. FSANZ recognises safety cannot be assured for 100% of consumers 100% of the time, this is equally well recognised and accepted by consumer representative organisations that educate members to be medically prepared for an adverse event at all times. While food labels can be seen as a useful part of a broader suite of risk management strategies for facilitating food choice, they should not be used as the sole source of information for matters as serious as food allergies.

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

This Proposal is to remove the requirement to declare certain information in relation to products that have been assessed as safe for the majority of allergic individuals.

Current labelling requirements may indicate to consumers that a food is allergenic to affected individuals, when in fact it is not. Therefore, the variation will allow a more informed choice. The requirement to bear other allergen declarations where they pose a safety risk will continue to enable informed consumer choice.

2.6.2.3 The prevention of misleading or deceptive conduct

Australian and New Zealand consumer laws will continue to apply to prevent misleading or deceptive conduct. See SD3

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk assessment, which is reflected in SD1.

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

The variation to the Code will promote consistency with international standards, in particular with the European Union and North America.

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

Progression of this Proposal will promote consistency with international standards, in particular with the European Union and North America, thereby facilitating competitiveness for Australian producers with overseas competitors for both domestic and other international markets, such as Asia.

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

Not applicable.

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

There are no written policy guidelines from the Australia and New Zealand Forum on Food Regulation that apply to this Proposal.

3 Transitional arrangements

The stock in trade provisions contained in Standard 1.1.1 will not operate in relation to the variations to Standards 1.2.3 and Schedule 10. The variations are deregulatory in nature and provide exemptions to current requirements. They will therefore come into effect on gazettal.

Attachments

A. Approved draft variations to the revised *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)

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

Food Standards (Proposal P1031 – Allergen Labelling Exemptions) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of this variation.

Dated [To be completed by Standards Management Officer]

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

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX.

1 Name of instrument

This instrument is the *Food Standards (Proposal P1031 – Allergen Labelling Exemptions) Variation*.

2 Commencement

This instrument commences on gazettal.

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

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

Schedule

[1] Standard 1.2.3 is varied by

[1.1] omitting subparagraph 1.2.3—4(1)(b)(i), substituting

(i) cereals containing *gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than:

(A) where these substances are present in beer and spirits; or

(B) glucose syrups that are made from wheat starch and that:

(a) have been subject to a refining process that has removed gluten protein content to the lowest level that is reasonably achievable; and

(b) have a gluten protein content that does not exceed 20 mg/kg;

(C) alcohol distilled from wheat;

[1.2] omitting subparagraph 1.2.3—4(1)(b)(v), substituting

(v) milk, other than alcohol distilled from whey;

[1.3] omitting subparagraph 1.2.3—4(1)(b)(vii), substituting

(vii) soybeans other than:

(A) soybean oil that has been degummed, neutralised, bleached and deodorised; or

(B) soybean derivatives that are a tocopherol or a phytosterol;

[1.4] inserting after subsection 1.2.3—4(2)

(3) To avoid doubt, subsection (1) does not require a declaration of the presence of a food or a product that is derived from a food or product that is exempt from declaration under paragraph 1.2.3—4(1)(b).

[2] Schedule 10 is varied by omitting the entry for “fats or oils” in the table to section S10—2, substituting

fats or oils	(a) The statement of ingredients must declare: (i) whether the source is animal or vegetable; and (ii) if the source of oil is peanut or sesame—the specific source name; and (iii) if the source of oil is soybeans and the oil has not been degummed, neutralised, bleached and deodorised—the specific source name; and (iv) if the food is a dairy product, including ice cream—the specific source of animal fats or oils. (b) This generic name must not be used for diacylglycerol oil.

Attachment B – Explanatory Statement

1. Authority

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

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

The Authority prepared Proposal P1031 to allow for specific exemptions from mandatory allergen declarations. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[2], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved the variation to Standard 1.2.3 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. These foods and ingredients are glucose syrups from wheat starch, fully refined soy oil, soy derivatives (tocopherols and phytosterols), and distilled alcohol from wheat or whey.

The Authority has also approved the variation to Schedule 10 to remove the requirement to declare in the statement of ingredients the specific source name for soybean oil that has been appropriately refined.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1031 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 12 August 2015 for a six-week consultation period.

[2] convening as the Australia and New Zealand Food Regulation Ministerial Council

Further targeted consultation was undertaken with key stakeholders including industry and consumer representatives. Advice on the risk assessment was sought from the Food Allergy and Intolerance Scientific Advisory Group.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.2.3 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

Item [1] of Schedule 1 of the variation amends Standard 1.2.3

Item [1.1] inserts sub-subparagraphs (A), (B) and (C) into subparagraph 1.2.3—(4)(1)(b)(i). Each sub-paragraph provides an exemption from the mandatory allergen declaration for cereals containing gluten. Sub-subparagraph (A) maintains the subparagraph's existing exemption for substances present in beer and spirits. Sub-subparagraph (B) provides a new exemption for glucose syrups derived from wheat that contain the lowest levels of gluten protein reasonably achievable and contain no more than 20 mg gluten/kg glucose syrup. Sub-subparagraph (C) provides a new exemption for alcohol distillates derived from wheat.

Item [1.2] amends subparagraph 1.2.3—(4)(1)(b)(v) by inserting the words 'other than alcohol distilled from whey'. The effect of this amendment is to exempt alcohol distillates derived from whey from the mandatory allergen declaration requirements for milk or products of milk.

Item [1.3] inserts sub-subparagraphs (A) and (B) into subparagraph 1.2.3—(4)(1)(b)(vii). Each sub-subparagraph provides an exemption from the mandatory allergen declaration requirements for soybeans. Sub-subparagraph (A) provides an exemption for oils derived from soybeans provided that the oils have been degummed, neutralised, bleached and deodorised. Sub-subparagraph (B) provides an exemption for tocopherols and phytosterols derived from soybeans.

Item [1.4] inserts new subsection 1.2.3—(4)(3) into the Standard. The new subsection makes clear that subsection 1.2.3—(4)(1) does not require the declaration of the presence of a food or substance derived from a food or product exempted from declaration under paragraph 1.2.3—(4)(1)(b). For example, the declaration of the presence of a product of vinegar derived from alcohol distilled from whey is not required as subsection 1.2.3—(4)(2) exempts alcohol distilled from wheat or from whey from declaration.

Item [2] of Schedule 2 of the variation amends the entry for 'fats or oils' in the Table to section S10—2 in Schedule 10. The effect of this amendment is to remove the requirement to declare in the statement of ingredients the specific source name for soybean oil that has been degummed, neutralised, bleached and deodorised.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

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

Food Standards (Proposal P1031 – Allergen Labelling Exemptions) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 2 of this variation.

Dated [To be completed by Standards Management Officer]

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

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX.

1 Name of instrument

This instrument is the *Food Standards (Proposal P1031 – Allergen Labelling Exemptions) Variation*.

2 Commencement

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions —2014 Revision.

3 Variation to Standards in the *Australia New Zealand Food Standards Code*

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

SCHEDULE

[1] **Standard 1.2.3** is varied by

[1.1] omitting subparagraph 1.2.3—4(1)(b)(i), substituting

"(i) cereals containing *gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than:

(A) where these substances are present in beer and spirits; or

(B) glucose syrups made from wheat starch with a gluten content not exceeding 10 mg/kg; or

(C) alcohol distilled from wheat;"

[1.2] omitting subparagraph 1.2.3—4(1)(b)(v), substituting

"(v) milk, other than alcohol distilled from whey;"

[1.3] omitting subparagraph 1.2.3—4(1)(b)(vii), substituting

"(vii) soybeans other than

(A) soybean oil that has been degummed, neutralised, bleached and deodorised; or

(B) soybean derivatives that are a tocopherol or a phytosterol;"

[2] Schedule 10 is varied by omitting the entry for "fats or oils" in the Table to section S10—2, substituting

"

fats or oils	(a) The statement of ingredients must declare: (i) whether the source is animal or vegetable; and (ii) if the source of oil is peanut or sesame—the specific source name; and (iii) if the source of oil is soybeans and the oil has not been degummed, neutralised, bleached and deodorised—the specific source name; and (iv) if the food is a dairy product, including ice cream—the specific source of animal fats or oils; and. (b) This generic name must not be used for diacylglycerol oil.