

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

Due date – 23 September 2015

The Victorian Departments of Health & Human Services and Economic Development, Jobs Transport & Resources (the departments) welcome the opportunity to provide comments on Proposal P1031 – Allergen labelling exemptions.

Proposal P1031 proposes removing mandatory allergen or gluten labelling requirements for certain glucose syrups made from wheat, fully refined soy oil, tocopherols and phytosterols derived from refined soy oil and alcohol distilled from wheat or whey.

From the FSANZ assessment report it is understood that:

- FSANZ, together with a working group from the Australian Food and Grocery Council's Allergen Bureau, identified the products for consideration for labelling exemption;
- FSANZ undertook two consultations with the Food Allergen and Intolerance Scientific Advisory Group to gain input from allergy clinicians in Australia and New Zealand;
- The products were chosen on the basis of available evidence that indicated that the method of their production would remove or reduce allergenic proteins or gluten to levels that are of negligible risk to sensitive consumers; and
- The products are also exempted by the EU (as part of a list of 13 exemptions) and, based on the absence of protein, may be eligible for exemption in the US and Canada.

The departments have reviewed the risk assessments provided by FSANZ and 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.

However, the departments have 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.

In 2014, the European Food Safety Authority (EFSA) provided a 'Scientific opinion on the evaluation of allergenic foods and food ingredients for labelling purposes'. In relation to gluten claims, EFSA concluded: The limit values of 20 and 100 mg/kg of gluten in "gluten-free" and "very low gluten" foods, respectively, help in managing the diet of most patients with coeliac efficiently.

The departments 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.

If an industry application is made, then the setting of a 10 mg/kg limit for gluten under Proposal P1031 could be seen as pre-empting the outcome of that application or as having undue influence on the outcome.

The broader issue of thresholds for allergens and gluten is the subject of ongoing national and international consideration. In the case of gluten, it is worth noting that initially the limit of detection was well in excess of 20 mg/kg (parts per million). It is now, as reported in the EFSA report referred to above, between 1 and 30 parts per billion for some products. The increasing sensitivity of testing will continue to limit the range of products available for coeliacs as long as the Code requirement of 'no detectable gluten' for gluten-free claims is in place.

The departments 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. However, currently there is sufficient evidence to indicate that distillates produced, under Good Manufacturing Practice (GMP), from any allergenic source will not pose a risk to sensitive consumers. 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 departments request that FSANZ also considers excluding distillates from other cereals and nuts from allergen labelling requirements.