Ministry for Primary Industries
Manatū Ahu Matua

23 September 2015

Project Officer Proposal P1031
Food Standards Australia New Zealand
PO Box 10559
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WELLINGTON 6036

[redacted]

Dear Sir/Madam

Proposal P1031 Allergen Labelling Exemptions – Call for Submissions

Thank you for the opportunity to comment on this proposal. The Ministry for Primary Industries (MPI) has the following comments to make.

General comments

Monitoring
MPI notes that the all of the allergen labelling exemptions being considered under P1031, have been introduced in the EU, and highly refined oils have been exempted in the USA. It would be interesting to obtain any data or information on the extent of the uptake of these exemptions and whether there has been any monitoring of the effects on reported reactions.

Glucose syrup derived from wheat starch
We note that the dietary exposure modelling has been based on the Australian population only (using the Australia National Children's Nutrition and Physical Activity Survey). The 2002 New Zealand National Children's Survey data is available to use, providing information on the mean, 90th, 95th and 97.5th percentile of confectionery and chocolate consumption for New Zealand children between 5-14 years of age. It may be possible that intakes of confectionery and chocolate are different between Australia and New Zealand.

Furthermore, we question why dietary exposures have been estimated for children only, not both children and adults in the risk assessment. In particular, coeliacs disease affects both children and adults. If it is assumed that children are likely to be higher consumers of confectionery and chocolate compared to adults, then this should be noted in the assessment.

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Although it is noted that consumption levels for confectionery and chocolate could not be added together (Table 5 in the risk assessment), it would be prudent to assume a 'worst case scenario' whereby the consumers of chocolate also consume confectionery, or vice versa. It is highly likely that a large proportion of those who consume chocolate also consume confectionery. We note that the number of consumers of confectionery and chocolate for both age groups is very similar.

There is no information or analytical data on glucose syrup manufactured in New Zealand. We consider there should be some discussion in the proposal as to why this has not been included, if indeed it has been considered.

Comments in relation to questions in Call for Submissions

Q1 – Is there further information about allergic consumers and health and safety aspects that you would like to provide for consideration? If so please support your comments with appropriate references and/or data.

It is our understanding that the Food Allergy and Intolerance Scientific Advisory Group (FAISAG) considered that 1mg would be a reasonable estimate of the NOAEL, and that the majority of wheat allergic patients would be protected if glucose syrups were prepared according to Appendix 2. MPI has discussed the 1mg level of wheat protein with a New Zealand allergen specialist not included on the FAISAG and it has been suggested that any level of wheat protein may elicit a response in a wheat allergic individual. Therefore, MPI suggests further consultation with allergen specialists to resolve any divergent views.

Q2 – Is there further information about production methods and/or residual protein levels of the substances discussed above that you would like to provide for consideration? If so, please support your comments with appropriate references or data.

MPI does not have further information to provide, but we do provide comments in relation to the proposed MLs in this submission under Q6.

Q3 – Do you have suggestions as to preferred means of communicating these changes to interested parties?

MPI suggests that all lines of communication are included, to ensure that consumers understand the change. This would include peak bodies that manage allergen information for consumers, Food and Grocery Councils in both countries, FSANZ and jurisdiction websites, health professionals managing allergic consumers, etc.

Q4 – Are there other implications for interested parties from the proposed exemptions from allergen declaration that may require consideration? If so, please provide any suggestions you may have as to how these might best be managed.

Some suppliers/manufacturers of food may wish to voluntarily declare the ingredients to which this proposal relates. For example, the declaration of soybean oil may still be preferred, to differentiate this oil from other

oils (eg palm oil). This is of course still permissible, but may present some confusion for consumers. We suggest that this is covered in communications to allergic consumers, so that they know the voluntary provision of this information is still permissible under the Food Code.

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.

Q5 – Do you have further considerations to add to the cost benefit analysis?

For the sector titled 'Consumers', a cost could be added that relates to the public health risk associated with ingredients used that do not comply with the maximum level of protein/production method. While this cost does not need to be quantified, it should be acknowledged.

Q6 – Do you agree/disagree with the proposed exemptions? Please provide information to support your comments.

Glucose syrup from wheat starch

The proposed maximum is 10 mg/kg, or 1 mg/100 g. We note that the maximum to elicit an allergic response is 1 mg wheat protein per meal. Therefore, as noted in the dietary modelling, a child consuming 100 g of confectionery made with glucose syrup would ingest this dose (1 mg). In reference to our general comments above, we consider that analysis of 2002 New Zealand National Children's Survey would be useful to confirm intakes of confectionery and whether 1mg wheat protein provides enough of a safety factor for wheat-allergic individuals.

The paper notes that less than 3 mg protein/kg is achievable, 95% of the time. A ML lower than 10 mg/kg could be considered, for example 5 mg/kg would provide a greater safety margin for wheat allergic individuals.

If this change is not made, the FSANZ Approval report could comment on the clinical significance for allergy sufferers, of 1 mg (or more) ingestion of wheat protein.

Fully refined soy bean oil

In SD1, section 1.11 Summary, there appears to be an error in the 4th paragraph. We presume that the figure of 50 micrograms is correct, and is derived from Table 3 on the previous page. If this is the case, this could be clearer. The figure 0.005 mg appears incorrect (and should be 0.05 mg). The concluding sentence in this paragraph may need revising, as 0.05 mg is not as "miniscule" as 0.005 mg.

We support the rationale and science that supports the FSANZ recommendation. However, the proposed draft variation at Attachment A may not be tight enough to fully capture the intent, ie fully refined oil (using a chemical process), that contains no more than a certain amount of protein. We note that 1 mg protein per kg

depending on the method used. We also note that the EFSA opinion and modelling was based on much lower levels of protein than these limits of detection, so for this reason, we think any maximum value (if agreed to) needs further consideration. We have left this as "xx in square brackets", in our suggested drafting changes below. The ML should be consistent with the value used in the safety assessment.

Our suggestion is to include the maximum protein per kg of oil. Including a maximum provides a more effective method of enforcement for jurisdictions. Including a ML that is linked to a production method does not mean industry has to test all soybean oil used, as industry can demonstrate compliance in other ways (for example, they can provide documentation that shows that refined bleached deodorised soybean oil is made to a particular production method, that ensures the level of protein is below the ML. However, including an ML that is linked to a production method provides increased confidence in the proposed amendment, and a tool that enforcement agencies can use, should they decide to test a raw material or finished product. MPI sees this as important, as the composition of oil and/or blended oils in imported oils is difficult to trace back to a raw material supplier, but product testing could be carried out in situations of uncertainty.

Suggested wording is as follows (our changes in italics):

> [1.3] (vii) soybeans other than
> (A) soybean oil that has degummed, neutralised, bleached and deodorised, *such that it contains less than [xx] mg soy protein per kilogram of oil;* or
> (B) soybean derivatives that are a tocopherol or a phytosterols; *containing less than [xx] mg soy protein per kilogram of the tocopherol or phytosterol*
>
> [2] fats or oils
> Amend (iii) as above, ie to include the maximum level of protein

<u>Soybean derivatives (tocopherols and phytosterols)</u>

Support, but suggested drafting changes shown above.

<u>Distilled alcohol from wheat or whey</u>

The approach is supported by MPI.

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Manager Food Science and Risk Assessment