



**Submission to  
Food Standards Australia New Zealand  
In relation to  
Proposal P1025: Code Review**

**27 September 2013**

**The Allergen Bureau Ltd**

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## The Allergen Bureau Ltd

The Allergen Bureau Ltd was established in 2005 as an initiative of the Australian Food & Grocery Council Allergen Forum, and currently operates independently on a membership basis. The overall objective of the Allergen Bureau is to share information and experience within the food industry on the management of food allergens to ensure manufacturers and consumers receive relevant, consistent and easy to understand information on food allergens.

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

The growth in the incidence of food allergens is an international phenomenon. The Allergen Bureau draws on and disseminates information from all over the world on food regulations and the latest scientific research on food allergens including emerging food allergens. The Allergen Bureau provides rapid responses to questions concerning the management of food allergen risks in food ingredients and manufactured foods in Australia and New Zealand.

The Allergen Bureau is the product of cooperation amongst competitors in the food industry, with national and multi-national food manufacturing and marketing companies, suppliers, importers, exporters, retailers and consumer groups cooperating and sharing information on managing the risks of food allergens in industry in the interests of consumers.

### Allergen Bureau Full Members:



**Allergen Bureau Associate Members (Category A, B & C):**

Advancing Food Safety	All Systems Go	Australasian Medical & Scientific Ltd
Bellamys Organic Pty Ltd	Domray Pty Ltd	FJ Fleming Food Consulting Pty Ltd
Hamilton Grant	Ingredion	Kadac Pty Ltd
Orange & Green Pty Ltd	Sci Qual International Pty Ltd	Vatmi Industries

## Introduction

The Allergen Bureau welcomes the opportunity to make this submission to Food Standards Australia New Zealand (FSANZ) in response to the call for submissions – *P1025: Code Review*.

The Allergen Bureau is aware that the Australian Food and Grocery Council (AFGC) have developed a comprehensive submission on the Code Review and have had the opportunity to review a draft of, and contribute to, this submission. A number of Allergen Bureau member companies have been involved in and contributed to the AFGC submission.

The Allergen Bureau supports the AFGC submission.

The Allergen Bureau submission will focus on matters related to allergen labelling.

## Allergen Bureau Position

### Opportunity for Reform

The Allergen Bureau believes that the current review could have afforded the opportunity for a broader review of the Australian New Zealand Food Standards Code (the Code) to determine whether the current Code is relevant to industry and other stakeholders in the context of the current global food market.

The industry has invested a significant amount of time and effort to provide feedback to FSANZ on this Code Review, which essentially does not move the industry forward in terms of regulatory reform.

The Allergen Bureau **supports** the principle of reviewing the Code. The Code in its current format is now over 10 years old and the awareness and management of allergens within the food manufacturing and supply system has progressed and improved during this time. For example, a significant development during this time has been the development and introduction of VITAL to guide industry in the risk assessment of cross contact allergens. An overview of VITAL is provided as **Attachment 1** to this submission.

There are also significant delays in potential reforms around allergens and allergen management – for example getting a proposal raised to exempt more highly refined allergens – this would have been an excellent opportunity to move ahead with a number of outstanding issues that have been delayed.

The Allergen Bureau believes that the opportunity for genuine reform has been missed – the time and effort dedicated to the current review by industry could have been better utilised focusing on a wider ranging review of the Code.

## The Current Review

Notwithstanding our comments in the previous section, the Allergen Bureau supports the goal of enforceability for the Code and the need for clarity in the drafting of the Code. This is essential to ensure a level playing field for manufacturers, importers and retailers.

The Allergen Bureau notes the intent expressed by FSANZ that no product should require reformulation or relabeling as a result of the Code Review. The Allergen supports this intent and is concerned that the proposed definition for ingredient is inconsistent with this stated intent. The proposed definition has significant implications for the labelling of cross contact allergens - this point is discussed further in the following section.

The Allergen Bureau **supports** the recommendation of the AFGC for a two year commencement period, for any resulting new Code, from the date of its gazettal. This will allow time for necessary training and documentation review and update.

The Allergen Bureau **supports** the AFGC in the requirement for both a regulatory impact assessment (RIA) and World Trade Organisation (WTO) notification.

## Specific Comments

### Section 1.17 Basic concepts—ingredient and compound ingredient

The draft Code contains the following "new" definition of ingredient:

- (1) For this Code, a food is an ingredient of a second food if:
  - (a) on its own or added to other foods, it is processed into the second food, including:
    - (i) by coming into contact with the substance or mixture of the second food as it is being processed, if any traces are left in the second food or are likely to be consumed with it; or  
*Example: cooking oil, flour dusted on bread dough, rice-paper wrappings, substances or foods used as processing aids.*
    - (ii) by being added into the substance or mixture of the second food, whether or not any traces are left in it; or  
*Example: alcohol that completely evaporates during cooking; baking powder that is completely transformed into other substances.*
  - (b) it comes into contact with the second food after processing, and traces of it are left in the second food.

The Allergen Bureau note that the criterion for allergen labelling remains essentially the same – section 1.57 – Mandatory declaration of certain substances in foods requires that:

(2) For subsection (1), the food may be present as:

- (a) an ingredient or an ingredient of a compound ingredient; or
- (b) a substance used as a food additive, or a component of such a substance; or
- (c) a substance or food used as a processing aid, or a component of such a substance or food.

The Allergen Bureau interpretation is that, based on the ingredient definition, allergens present due to cross-contact will be considered to be ingredients and will therefore require labelling.

The outcome of this interpretation is that allergens currently labelled as cross contact allergens in the form of a precautionary statement would now be required to be included in the ingredient list. This is irrespective of the amount of the allergen present, effectively negating the premise of VITAL which sets an action level triggering the requirement for a precautionary labelling statement – “may be present”.

The consequence of this changed definition with respect to allergen declaration is:

1. Relabeling of product to move the precautionary allergens to the ingredient list;
2. Removal of the precautionary labelling statement; and
3. Labelling of allergens which were previously below the level of VITAL action level 1 (no labelling required) in the ingredient list.

Such a relabeling exercise would present a significant cost to industry and present no identifiable benefits to the allergic consumer. In fact, the requirement to label allergens that were previously below VITAL action level 1 would mean that some products would no longer be suitable for allergic consumers, denying them products which they had, up until this time, consumed as part of their diet.

This will not only affect the industry in Australia and New Zealand but will have impact on imported foods.

**The Allergen Bureau believes that the definition of ingredient is incorrect and must be reviewed by FSANZ to ensure that the status of cross contact allergens and the VITAL process is maintained.**

## **Section 1.57 – Mandatory declaration of certain substances in foods**

The scope of the provisions regarding gluten has been reworded without any apparent rationale.

The current Code states:

*“Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively.”*

The version in P1025 states:

*“wheat, rye, barley, oats and spelt and hybridised strains of those cereals (that is, cereals and cereal products containing gluten), other than where these substances are present in beer or spirits;”*

**The Allergen Bureau recommends that the wording in the current Code is reinstated for continuity and to prevent confusion.**

## **Conclusion**

The Allergen Bureau considers that the issues identified in this submission in relation to their impact on allergen labelling and VITAL are significant and warrant review and consultation with industry and other key stakeholders.

The Allergen Bureau supports the recommendation of the AFGC for the establishment of a joint FSANZ Stakeholder Working Group to progress this task ahead of the next round of public consultation.

The Allergen Bureau requests that FSANZ undertake a Regulatory Impact Assessment (RIA) in relation to P1025 so that the cost impact of the revised Code on Industry and other stakeholders is fully assessed and weighed against the benefits of the review.

The Allergen Bureau requests that FSANZ notify the WTO of the proposed changes to minimise impacts on Australia’s exports.

## **Attachment 1 - VITAL**

### **VITAL Background**

Food allergens may be present in a food due to intentional inclusion as part of a recipe and, may also be present due to unintentional cross-contact. Cross-contact can occur at any point in the supply chain of an ingredient due to the type of ingredients used or through the use of shared equipment and processes during manufacture. Even under conditions of Good Manufacturing Practice (GMP) cross-contact may be difficult to eliminate entirely, leading manufacturers to use precautionary advisory statements to advise allergic consumers.

In 2007, the Allergen Bureau established the VITAL (Voluntary Incidental Trace Allergen Labelling) system as a standardised allergen risk assessment tool for food producers. VITAL provides a single simple standardised precautionary statement available to assist food producers in presenting allergen advice consistently for allergic consumers. The statement is applied to food based on a risk assessment which involves the quantification of possible sources of cross contact. Each product is evaluated for the likely sources of allergen cross-contact from raw materials (ingredients) and the processing environment. The processing environment review includes manufacturing lines, environment and storage and consideration of processes applied to either negate or reduce the cross contact risk. The evaluation results in an Action Level for which precautionary labelling is or is not recommended.

In the original version of VITAL, the Action Levels were based on the threshold doses of protein from allergenic foods for subjective and objective responses cited by the 2006 U.S. Food & Drug Administration (FDA) Threshold Working Group. Because there was some uncertainty surrounding the FDA estimates and the general paucity of available data on threshold doses at that time, a 10-fold uncertainty factor was also applied.

Furthermore, although it is generally recognized that food-allergic individuals react to the dose of protein consumed, rather than its concentration in food, in order to encourage uniform uptake by the food industry, the original Action Levels in VITAL were expressed as concentrations (parts per million) of protein (milligrams) in a 5 g reference serving size (a teaspoon).

The original version of VITAL 1 Grid comprised 3 Action Levels.

- Action Level 1 – Concentration of allergen in food is below the concentration of allergen protein corresponding to the threshold dose – Precautionary labelling not recommended.
- Action Level 2 - Concentration of allergen in food equals or exceeds the concentration of allergen protein corresponding to the threshold dose –



Precautionary labelling recommended using a standard “May be Present: *allergen*” statement.

- Action Level 3 - Concentration of allergen in food exceeds by 10 fold the concentration of allergen protein corresponding to the threshold dose – Definitive labelling recommended e.g. “Contains allergen: *allergen*”.

## **The VITAL Scientific Expert Panel (VSEP)**

In 2010, the Allergen Bureau commenced a review of VITAL. Because of the emergence of substantial new literature on allergen thresholds, the Allergen Bureau established a Scientific Expert Panel, in collaboration with the Food Allergy Research & Resource Program (FARRP) of the University of Nebraska & the Netherlands Organisation for Applied Scientific Research (TNO) to provide advice on the scientific basis for Action Levels in VITAL. The VITAL Scientific Expert Panel (VSEP) met in Sydney, Australia, in January 2011 and thereafter worked out of session.

Members of The VSEP are Steve Taylor (FARRP, Panel Chairperson), Joseph Baumert (FARRP), Rene Crevel (Unilever), Geert Houben (TNO), Simon Brooke-Taylor (Allergen Bureau consultant, Australia), and Katie Allen (Paediatric Gastroenterologist/Allergist, Australia). During the process, the Panel received considerable assistance from Ben Remington (FARRP), Astrid Kruizinga (TNO), Ellen Dutman (TNO), and Harrie Buist (TNO). The VSEP sought to apply an approach, described previously by Crevel et al., 2007, to establish dose distribution relationships for the allergic population using statistical modelling of data from oral clinical challenges of individual patients. This approach introduces the concept of a predicted population eliciting dose (ED), where ED<sub>p</sub> refers to the dose of allergen that is predicted to produce a response in p% of the allergic population. The ED is determined from statistically derived population dose distribution curves constructed using the data from clinical challenge studies. The approach enables the identification of a dose of an allergen (ED<sub>p</sub>) at which a proportion of the allergic population would be likely to react to but, importantly, does not identify a dose below which no allergic individual would react.

The VSEP drew data on individual NOAELs and LOAELs from published clinical literature independently sourced by scientists at the Food Allergy Research & Resource Program (FARRP) at the University of Nebraska and at TNO in the Netherlands. These data sets were merged and supplemented with unpublished clinical data from the Netherlands and Germany (gathered by TNO) and partially completed FARRP data. Publications were selected based upon the criteria outlined previously (Taylor et al., 2009) in particular focusing on results from low-dose oral challenges.

Challenge data were expressed as milligram of allergen protein using either data provided by the study authors or by reference to standard food composition tables.

The data were assessed in terms of both discrete and cumulative (all doses given up to the point of reaction) data sets. The first objective symptoms of an allergic response occurring in an individual were used as the basis for the LOAEL with the NOAEL set at the previous dose in the clinical protocol. Interval-Censoring Survival Analysis as described previously by Taylor et al., 2009, was used to determine the true threshold dose, which by definition, lies between the NOAEL and LOAEL doses. Individuals reacting to the first challenge dose were treated as left-censored, while individuals failing to respond to the uppermost challenge dose, but who had clear histories of allergic reaction to offending food, were treated as right-censored. Data sets were considered of higher quality if more individual data points were interval censored.

The data were fitted to parametric models using the SAS LIFEREG procedure (SAS v9.1) as described previously (Taylor et al., 2009). Three parametric models (log normal, log logistic, Weibull) were used to fit the data for each allergenic food for adults, children, and combined adults and children and for discrete doses and cumulative doses.

Sufficient low-dose clinical challenge data were obtained to attempt modelling for peanut, milk, egg, hazelnut, soybean, wheat, sesame seed, mustard, lupin, shrimp (representative of crustacean shellfish), cashew, celery, and fish. No data from low-dose clinical challenges were found for other tree nuts, other crustacean shellfish (crab, lobster), or any molluscan shellfish.

The results of the VSEP analysis have been described in detail (Allen et al 2013; & Taylor et al 2013).

In summary, the eliciting doses for all three models (log normal, log logistic, and Weibull) were determined, with preference being given to the model with the best fit at low doses, as determined by statistical and visual examination. Where sufficient data existed, in addition to the combined data, distributions were modeled separately for infants and children versus adults. The challenge doses were normalized in all cases to milligram of protein from the allergenic food.

Data from large numbers of subjects were available for peanut, milk, egg, and hazelnut. Smaller amounts of individual threshold data were found for soybean, wheat, cashew, mustard, lupin, sesame seed, shrimp, celery and fish.

### ***Peanut***

Peanut thresholds were obtained for 750 individuals (489 published and 261 unpublished), comprising: 584 children, 99 adults, and 67 of undetermined age; 30 left-censored and 132 right-censored. The peanut data set was considered to be excellent.

The VSEP recommended that the VITAL Reference Dose be set at 0.2 mg peanut protein, based on the ED01 values of the log normal and log logistic distributions based on discrete

and cumulative doses for both adults and children.

### ***Milk***

Milk thresholds were obtained for 351 individuals (222 published studies and another 129 unpublished), comprising: 323 children, 25 adults and 3 of undetermined age; 59 left-censored and 19 right-censored. Overall, the milk data set was considered to be excellent.

The VSEP recommended that the VITAL Reference Dose be set at 0.1 mg milk protein, based on the ED01 values of the log normal and log logistic distributions based on discrete and cumulative doses for both adults and children.

### ***Egg***

Egg thresholds were obtained for 206 individuals (110 published and 96 unpublished), comprising: 174 children, 12 adults, and 20 of undetermined age; 24 left-censored and 33 right-censored. Overall, the egg data set was considered to be excellent. The data set pooled data for both raw and cooked eggs.

The VSEP recommended that the VITAL Reference Dose be set at 0.03 mg egg protein consistent with the ED01 and 95% lower confidence interval of the ED05 values of the Weibull and other distributions and based on discrete and cumulative doses for children.

### ***Hazelnut***

Hazelnut thresholds were obtained for 202 individuals (29 published and 173 unpublished), comprising: 61 children and 141 adults; 4 left-censored and 67 right-censored. Overall, the hazelnut data set was considered to be good but would be enhanced by publication of the unpublished data.

The VSEP recommended that the VITAL Reference Dose be set at 0.1 mg hazelnut protein, based on the ED01 and 95% lower confidence interval of the ED05 values of the log logistic and other distributions and also on discrete and cumulative doses for adults and children.

### ***Soybean***

Individual soybean thresholds were obtained for 80 individuals (43 individuals published and 37 unpublished), comprising: 33 children, 25 adults, and 22 of undetermined age; 6 left-censored and 28 right-censored. Overall, the soybean data set was considered to be sufficient. The VSEP observed that some challenge studies with soy flour indicate reasonably high individual soybean thresholds, whereas studies using soy milk with subjects selected on the basis of a history of adverse reactions to a particular brand(s) of soy milk appear to indicate lower individual thresholds.

The VSEP recommended that the VITAL Reference Dose be set at 1.0 mg soybean protein, consistent with the 95% lower confidence interval of the ED05 values of the log normal and other distributions based on discrete and cumulative doses for children and adults having

soy flour challenges. The VSEP noted that this level may not completely protect certain individuals sensitive to soy milk.

### ***Wheat***

Individual wheat thresholds were obtained for 40 individuals<sup>1</sup> (37 published and 3 unpublished), comprising: 28 children and 12 adults; 5 left-censored and 1 right-censored. Overall, the wheat data set was considered to be sufficient.

The VSEP recommended that the VITAL Reference Dose be set at 1.0 mg wheat protein, consistent with the 95% lower confidence interval of the ED<sub>05</sub> values of all three distributions based on discrete and cumulative doses for adults and children. The VSEP noted that wheat-allergic consumers would be largely protected by foods containing <20 ppm gluten.

### ***Cashew***

Cashew thresholds were obtained for 31 children (all unpublished); 1 left-censored and 16 right-censored. Overall, the data set was considered to be marginally sufficient.

The VSEP recommended that a provisional VITAL Reference Dose only be set at 2.0 mg cashew protein, consistent with the 95% lower confidence interval of the ED<sub>05</sub> values of all three distributions based on discrete and cumulative doses for children.

### ***Mustard***

Mustard thresholds were obtained for 33 individuals (all published), comprising: 9 children, 9 adults, and 15 of undetermined age; 2 left-censored and 10 right-censored. Overall, the data set was considered as sufficient.

The VSEP recommended that the VITAL Reference Dose be set at 0.05 mg mustard protein, consistent with the 95% lower confidence interval of the ED<sub>05</sub> values of all three distributions based on discrete and cumulative doses for children and adults.

### ***Lupin***

Lupin thresholds were obtained for 24 individuals (9 published and 15 unpublished). Comprising: 9 children and 15 adults; 2 left-censored and 7 right-censored. Overall, the data set was considered sufficient.

The VSEP recommended that the VITAL Reference Dose be set at 4.0 mg lupin protein, consistent with the 95% lower confidence interval of the ED<sub>05</sub> values of the log normal and log logistic distributions based on discrete and cumulative doses for children and adults.

### ***Sesame seed***

Sesame seed thresholds were obtained for 21 individuals (all published), comprising: 6 children, 13 adults, and 2 of undetermined age.; 2 left-censored and 1 right-censored.

Overall, the sesame seed data set was considered as marginally sufficient.

The VSEP recommended that the VITAL Reference Dose be set at 0.2 mg sesame seed protein, consistent with the 95% lower confidence interval of the ED05 values of the three distributions based on discrete and cumulative doses for children and adults.

### ***Shrimp***

Shrimp thresholds were obtained for 48 adults (25 published and 23 unpublished); 26 right-censored and none left-censored. Overall, the shrimp data set was considered as marginally sufficient.

The VSEP recommended that the VITAL Reference Dose be set at 10 mg shrimp protein, consistent with the 95% lower confidence interval of the ED05 values of the three distributions based on discrete and cumulative doses for adults.

### ***Celery***

Celery thresholds were obtained for 39 individuals (12 published and 27 unpublished), comprising: 27 adults and 12 of undetermined age; 15 left-censored and 4 right-censored. The celery data set was considered as insufficient to allow an estimate of ED values.

### ***Fish***

Fish thresholds were obtained for 19 individuals (15 published and 4 unpublished), comprising: 18 adults and 1 child; 6 left-censored and 2 right-censored. The data set covered challenges with several different fish species, including cod (10), catfish (5), snapper (1), halibut (1), tuna (1), and tilapia (1). The fish data set was considered as insufficient to allow an estimate of ED values. The VSEP provided the scientific rigour that underpins the VITAL system and the group will continue to be supported on an on-going basis by the Allergen Bureau as the key scientific experts.

### ***Other Tree Nuts***

The VSEP was unable to locate sufficient data on individual thresholds for any other tree nuts, including walnut, pecan, almond, pistachio, brazil nut, macadamia nut, pine nut.

## **VITAL 2.0**

The Allergen Bureau adopted revised VITAL Action Levels, based on the VSEP recommendations, in VITAL 2, which was launched in 2011. In implementing the VSEP recommendations the Allergen Bureau:

- Adopted the recommended Reference Doses for shrimp and hazelnut as surrogates for all crustacea and tree nuts respectively. In adopting the level for shrimp, although all of the data originated from a single species of US caught shrimp, the

Allergen Bureau had regard to verbal advice that the data is consistent with data were emerging in EUROPREVALL studies.

- Capped the calculation of Action Level 2 (the threshold for precautionary labelling) for wheat allergy such that the threshold does not exceed 20ppm so applicable for both the wheat allergic and coeliac populations. The Coeliac Australia “Crossed Grain” logo also supports a threshold of 20ppm..
- Adopted all other VSEP recommendations
- Retained the Reference Dose of 0.1mg protein for fin fish from VITAL 1 (based on the FDA thresholds working party report), as no VSEP recommendation was made.

In addition, the standard reference serving (5mg) was removed and replaced, in the VITAL Grid table, with a Reference Amount field in which the manufacturer is required to enter the typical serving size or normal consumption amount for their food. The Action Levels (ppm allergen protein) for the specific food are then calculated, using the Reference Dose of allergen (mg total protein) and the identified Reference Amount of food (gm).

The VITAL 2 Grid contains two Action Levels:

- Action Level 1 – Concentration of allergen in food is below the concentration of allergen protein calculated from the Reference Dose and Reference Amount – precautionary labelling not recommended.
- Action Level 2 - Concentration of allergen in food equals or exceeds the concentration of allergen protein calculated from the Reference Dose and Reference Amount – precautionary labelling recommended using a standard “May be Present: *allergen*” statement

The previous Action Level 3 has been removed from the VITAL Grid. When the review of a food indicates that the level of an allergen protein may exceed the Reference Dose by 10 fold or greater, manufacturers are advised in VITAL 2 to review their manufacturing operation in the context of Good Manufacturing Practice.

## **The VITAL Procedure: Implementation of VITAL by a food manufacturer**

The Food Industry Guide to the VITAL Program (the Guide) can be downloaded freely from the Allergen Bureau website. The Guide contains background information about VITAL, the application of VITAL (the VITAL Procedure) and additional information about the use of allergen analysis and the VITAL Decision Tree. The Guide is the primary reference for food manufacturers to implement VITAL.

The pre-requisites for VITAL are that the program should be used as part of a HACCP (Hazard Analysis Critical Control Point) food safety plan and that the VITAL assessment is performed by appropriately trained food safety personnel.

An assessment is undertaken to identify and quantify cross-contact allergens that may be unintentionally incorporated into the product to be assessed either through the ingredients or due to the environment in which the product is manufactured. The allergen status of each ingredient is determined, including intentionally added (inherent) allergens and cross-contact allergens which may be incorporated during the supply chain. Cross-contact allergens due to shared manufacturing lines, equipment, tools and/or people at the site of manufacture of the product to be assessed must be identified and quantified.

The Reference Amount or serving size must be determined and is the maximum amount of a food eaten in a typical eating occasion. This may be the same as the “serving size” on the nutrition information panel or it may be appropriate that the Reference Amount is considered to be the whole product as presented to the consumer. The Action Level threshold is determined using the Reference Amount and the Reference Dose and is compared to the total milligrams of total allergen protein in the finished product for each cross-contact allergen. Where this total falls in:

- Action Level One, no precautionary labelling is recommended, and
- Action Level Two, precautionary labelling is recommended.

To assist manufacturers in storing the allergen information about each product and completing the calculations for VITAL, the Allergen Bureau has produced a Microsoft Excel-based VITAL calculator which guides the user through the VITAL calculations. The allergen information, the Reference Amount and any relevant assumptions can be entered (and stored) in the Microsoft Excel VITAL Calculator. A report is produced which includes labelling recommendations for the product being assessed.

In addition the Allergen Bureau has licensed training providers to provide short courses to industry to educate them in allergen management and VITAL and also maintains a VITAL support phone and email service.

A complete set of the VITAL documentation may be downloaded from the Allergen Bureau

website <http://www.allergenbureau.net/vital/vital-downloads>. In addition a Microsoft Excel copy of the VITAL grid, demonstrating the calculation of Action Levels from the Reference Dose and Reference Quantity is attached to this submission.

## References

Allen, K. et al. Clinical considerations in the development of allergen management thresholds for precautionary labelling of foods- VITAL 2.0 2013 (in preparation)

Crevel, R.W.R., Briggs, D., Hefle, S.L., Knulst, A.C., Taylor, S.L., 2007. Hazard characterisation in food allergen risk assessment: the application of statistical approaches and the use of clinical data. *Food Chem. Toxicol.* 45, 691-701.

Taylor, S.L. Establishment of reference doses for residues of allergenic foods: report of the Scientific Expert Panel. *Food Chemical Toxicology* 2013 (in prep).

Taylor, S.L., Crevel, R.W.R., Sheffield, D., Kabourek, J., Baumert, J., 2009. Threshold dose for peanut: risk characterization based upon published results from challenges of peanut-allergic individuals. *Food Chem. Toxicol.* 47, 1198-1204.