

VITAL Q&A

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1. General Questions about VITAL

Q What is VITAL?

A VITAL (Voluntary Incidental Trace Allergen Labelling) is a risk-based methodology for food producers to use in assessing the impact of allergen cross contact to indicate appropriate precautionary allergen labelling. The application of VITAL aims to avoid indiscriminate use of precautionary labelling and thereby preserve its value as a risk management tool and its role in minimising risk to allergic consumers.

Q It all looks too hard and involved – as a food manufacturer why should I do this?

A The use of VITAL can assist a manufacturer to identify and label allergens in a risk-based and consistent method. Implementation of VITAL is consistent with HACCP and protects the interests of food manufacturers by ensuring that the presence of allergens in foods due to cross contact are appropriately labelled. Also, by identifying cross contact allergens, VITAL encourages manufacturers to eliminate or reduce cross contact allergens.

Q What is the benefit to industry of VITAL?

A VITAL represents a uniform, risk-based approach to allergen cross contact identification and precautionary labelling. Implementation of VITAL across industry builds confidence by ensuring that allergen precautionary statements provide reliable and meaningful information to allergic consumers.

Q Who is using it – what sort of take up has occurred in the food industry?

A There are a number of food manufacturers who are currently using the VITAL tool. Food retailers are increasingly expecting manufacturers to utilize VITAL for risk assessment of cross contact allergens on their pre-packaged, private label branded products.

Q Where do I get the information?

A Information about VITAL can be freely downloaded from the Allergen Bureau website.

Q How often do I need to check for updates?

A VITAL users should check the Allergen Bureau website each time they use the calculator to see if they have the most recent version. It is also recommended that users register with the Allergen Bureau so that they can receive any relevant updates.

Q Who developed and maintains VITAL?

A VITAL was developed by a project team under the Allergen Forum of the Australian Food and Grocery Council (AFGC). VITAL is now managed by the Allergen Bureau.

Q What is the cost of implementing VITAL?

A The VITAL program can be freely downloaded from the vitalallergen.com website. VITAL should be used as one component of the risk assessment for a food business.

2. Ingredient Listings and the “May be Present” precautionary statement

Q Do I have to use the “may be present” statement?

A Yes, this is the only precautionary statement to be used with the VITAL risk assessment (ie May Contain XXX, Contains Traces of XXX and other precautionary statements are not to be used in conjunction with the VITAL tool).

Q Why is the “may be present” statement required to be used with VITAL?

A The “May Be Present” statement is the only precautionary statement to be used with VITAL and indicates to the consumer a sporadic, unavoidable cross contact with an allergen which may present a personal risk.

Q Is there a minimum print size for the “May be present” statement?

A All printing on a label should comply with any requirements of the Food Standards Code. Further information about Labelling can be found in the AFGC “Food Industry Guide to Allergen Management and Labelling” at www.allergenbureau.net.

Q My product contains products from wheat, rye, barley, oats or spelt that do not contain gluten. There is no detectable gluten in the products so do I have to declare them on the label?

A The Australia New Zealand Food Standards Code mandates that cereals containing gluten and their products must be declared on the product label. There is no exemption for highly refined products derived from a gluten source and these products should be included in the ingredient listing if they are intentionally formulated into the product. When using the VITAL calculator, answer “yes” when asked if the ingredient contains gluten.

Q My product contains sulphites at less than 10ppm – do I need to include them on the allergen summary (Contains) statement?

A The Australia New Zealand Food Standards Code requires mandatory labelling of sulphites where they are present at concentrations of 10mg/kg or more. Where sulphites are present at less than 10mg/kg, it is not necessary to declare them either in the allergen summary statement or the ingredient listing.

Q. Can I use VITAL to confirm an allergen-free statement?

A Allergen-free statements should only be used where supported by an Allergen Management Plan which may include programs for allergen testing of ingredients/finished products, cleaning validation, a VITAL assessment and other relevant facets.

It would not be appropriate to use an allergen-free statement

- where there is an ingredient, compound ingredient, processing aid or additive derived from a source containing the relevant allergen, regardless of amount added or degree of refining.
- Where a VITAL assessment identifies cross contact from any source, at any level, from the relevant allergen.

Lactose-free and gluten-free statements are specifically covered in the Food Standards Code Standard 1.2.8 (Clauses 15 & 16).

3. VITAL Calculator

Q How do I use the calculator? What goes in each box?

A Each worksheet in the VITAL calculator provides directions about how to fill it out and what information it put in each cell.

Q My food has more than 20 ingredients. How do I use the calculator for it?

A Select a number of ingredients and use a separate worksheet for them. Then treat them as a compound ingredient in the worksheet for the finished food.

Q A colleague gave me a copy of the calculator. I've filled it out but it isn't giving me a result?

A The VITAL calculator contains hidden formulas and macros. If the worksheets are individually copied or extracted these elements may be lost. Download a new copy of the calculator from the vitalallergen.com website.

Q Please explain how the "Concentration: (e.g. Baking) Enter as % reduction, [Final baked product / Original unbaked product weight]" cell works in the VITAL calculator.

A If you are losing 5% of the original weight of the product in cooking, you would enter 95% into the "Concentration" cell. The term % reduction is not strictly correct and will be amended in the next review of the VITAL calculator.

Q Do I have to use the VITAL calculator?

A The VITAL calculator is provided as a tool to assist with calculations. The concentration of cross contact protein can be manually calculated and compared against the VITAL grid. The calculator is not a mandatory component of VITAL.

4. Legal Issues

Q Is VITAL mandatory?

A VITAL is an initiative of the Australian Food and Grocery Council and its adoption is voluntary. However, uniform adoption of VITAL across the industry will assist in providing consistent information about cross contact allergens in foods. Food retailers are increasingly expecting manufacturers to utilize VITAL for risk assessment of cross contact allergens on their pre-packaged private label branded products.

Q Are there penalties for manufacturers who claim to use VITAL, but haven't done it or haven't done it correctly?

A VITAL is a voluntary program and is not a legal requirement. It is the manufacturers responsibility to adequately assess and control risk and to label appropriately – VITAL can be used as a tool to assist in this process. The Allergen Bureau will be monitoring the use of VITAL through market surveys and may contact companies if there are concerns about the inappropriate use of VITAL.

Q Does FSANZ endorse the use of VITAL?

A FSANZ was consulted and provided input during the development of VITAL. FSANZ develops Food Standards but does not enforce or undertake interpretation of food law and accordingly it is not in a position to endorse VITAL.

Q If I run the VITAL assessment and find that there are some cross contact allergens that are not currently on the label, how long do I have to make the change to the packaging?

A When a VITAL assessment shows a cross contact at Action Level 2, you should work towards resolving this issue either by eliminating or reducing the cross contact allergen or reviewing the ingredient listing and/or precautionary statement on the packaging.

5. VITAL Procedure

Q How can I work out the cross contact on manufacturing equipment which may carryover from one product to the next?

A Determination of the amount of carryover product should be done in consultation with those most familiar with the procedures and manufacturing equipment. The method will vary depending on equipment and product type. It is important to work out the maximum amount of carryover that could occur during normal processing conditions. For example, if you do a water flush between each product, then you should consider the amount of product left in the line after the water flush.

Some examples of how to determine carryover are:

- weighing the carryover material e.g. a dry blend manufacturer may vacuum the inside of the equipment and then weigh the dust. A bakery could scrape out any leftover material and weigh it.
- visual determination
- calculation of the volume of product in pipes could be used where weighing or visual determination is not available

Q We have a very complicated plant with lots of allergens and many products – how can we simplify VITAL?

A You should follow the standard VITAL procedure. When looking at cross contact from processing, it may be possible to work out a small number of possible scenarios for allergen carryover.

Q Our factory has an excellent Allergen Management Plan and validated cleaning between each product. What should I put for cross contact allergens via processing?

A VITAL is a tool to assist with an Allergen Management Plan and should not replace any part of your existing Plan. The determination of the amount of cross contact product should be done assuming the maximum amount of carryover that could occur during normal processing conditions. If your procedures control the amount of cross contact, then it may be suitable to use “Oppm” for the amount of cross contact due to processing.

Q Can I use the VITAL grid to work out if I need to declare allergens from ingredients added at tiny amounts or highly refined substances from allergenic sources?

A VITAL is only to be used for cross contact substances. Please refer to the Australia New Zealand Food Standards Code Standard 1.2.3 Mandatory Warning and Advisory Statements and Declarations which requires the mandatory declaration of the presence in a food any of the listed allergenic substances when present as an ingredient, an ingredient of a compound ingredient, a food additive or component of a food additive or a processing aid or component of a food processing aid. There is currently no exemption for highly refined substances from allergenic sources and no threshold below which intentionally added substances from an allergenic source are exempt from declaration.

Q How do you validate the theoretical calculations if the levels of allergens are estimated to be below the limit of detection?

A VITAL should consider the maximum possible carryover of cross contact allergens – it is unlikely that a small random sample done to validate VITAL calculations will indicate the maximum level of contamination. However, validation may be important as part of your Allergen Management Plan – e.g. validation of cleaning. Refer to the ‘Food Industry Guide to the VITAL Program’ for further information about VITAL and Allergen Analysis.

Q Does VITAL propose a sampling plan or number of product lots that should be tested in order to confirm presence or absence of allergen residues for the VITAL grid?

A No, VITAL can be applied to any food manufacturing process. VITAL does not, therefore, prescribe sampling plans or testing procedures. Any sampling plan should be determined by the manufacturer as part of their risk assessment/HACCP/quality plan.

Q Does VITAL propose manufacturers to set up an active surveillance program to monitor how effective their labelling strategy has been?

A No, this is not a requirement of VITAL, however, manufacturers may wish to monitor effectiveness by asking allergic individuals whether they are consuming their products and whether they find the VITAL labelling format helpful.

Q How do I work out the amount/level of allergen in my food?

A The VITAL Procedure can guide you through the steps to work out allergens from ingredients and from cross contact. VITAL considers contamination from allergens via cross contact from the manufacturing of ingredients and from the final product’s manufacturing environment. The amount of cross contact allergens from ingredients should be determined with your supplier – the Product Information Form has been developed to assist with the provision of information for the VITAL assessment. The amount of cross contact allergens at your manufacturing facility should be determined by conducting an audit of the process and could include the amount of carry over food via line/people/foods and hang up points. Use food databases, food technology literature, specifications or the VITAL Allergenic Protein levels of the Allergen Bureau website to determine the level of total protein. The VITAL tool can assist with calculations to determine action level for labelling.

Q Do the action levels in the grid correspond to the limits of detection for each allergen?

A No. The action levels have been determined using data from clinical trials in which the foods in question were consumed by people with known allergies. They are expressed in terms of total protein as this is what is normally reported in the clinical trials. The levels were determined independently of the available test methodology, which normally measure specific allergenic proteins.

Q I've identified a food/ingredient in our plant that may contain an allergen & which may be in cross contact with other products. How do I determine the level of allergenic protein in this ingredient?

A VITAL uses the total protein content of the food/ingredient. The typical protein content of foods can be found in food databases, food technology literature or specifications. There is also a list of standard protein levels of common foods on the Allergen Bureau website.

Q How do I convert mg/Kg to ppm or mg/kg?

A There are 1,000 milligrams in a gram. Parts per million (ppm) is an equivalent measure to mg/kg as there are 1 million milligrams in a kilogram. A quick way to convert gms/100gm to mg/kg is to multiply the grams by 10,000. For example, 2 gms /100gm (or 2%) x 10,000 = 20,000 mg/kg

Q Where can I find information on the amount of protein in a particular food?

A The typical protein content of foods can be found in food databases, food technology literature or specifications. There is also a list of standard protein levels of common foods on the Allergen Bureau website.

Q Is VITAL applicable for calculating allergen cross contact and testing for allergen cross contact?

A VITAL can be used to calculate potential allergen cross contact and to determine labelling recommendations based on risk. Allergen testing can be done as a validation step but is not necessary for using the VITAL tool.

Q How should I consider sulphites when applying VITAL?

A Added sulphites must be declared when present at a level of 10mg/kg or greater. There is no requirement for "may be present" type statements at lower levels or for sulphites that are naturally produced in the food (for example by fermentation). Sulphites are not included in VITAL and should be assessed separately.

Q What is the expected level of documentation to support that I have effectively performed VITAL?

A Documentation should be kept to support all decisions, calculations and assumptions which were used to determine if a precautionary statement is required. For example, some documentation that may be useful would be the completed VITAL template and calculator, Product Information Forms/Specifications, correspondence with suppliers, risk assessments, details about hang up points, any validation results etc.

Q If I test my final product and find the cross contact allergen only 2% of the time, do I need to declare the allergen?

A VITAL does not work on probability/frequency. Under the VITAL process, if a level of cross contact allergen is found to be at Action Level 2 then it should be declared on the label. VITAL is based on the maximum possible amount of cross contact allergen contamination under normal processing conditions.

Q If I pack the same product across different manufacturing sites, and each site has a different action level for cross contact allergens, do I need to have different packaging for each site?

A This would be a decision that your company would need to make. Options would be either to use the "worst case" for labelling or have different packaging for each site.

Q. How should I consider lactose or other non-protein fractions from allergenic foods which are identified as cross contact substances?

A. Non-protein foods (such as lactose) are not covered in the scope of VITAL and should be assessed separately.

6. Computer Issues

Q I am having trouble downloading the VITAL calculator.

A The VITAL calculator contains macros – you may need to have the security restrictions on your computer temporarily relaxed in order to download this document. Talk to your IT department. If your computer is not part of a network, you may need to change your macro security settings in Microsoft Excel.

7. Consumers and VITAL

Q What is the benefit to allergic consumers if industry uses VITAL?

A The adoption of VITAL across the food industry will provide consumers with consistent information about cross contact allergens in food.

8. Auditing and VITAL

Q Is there a Certification system for those who are using VITAL?

A No. VITAL is a voluntary process however, it is expected that it would be incorporated and audited within a company's existing food safety management system. There is a VITAL Auditor Guide available on the Allergen Bureau website.

9. PIFs and Other Supplier Information

Q Do I have to use the actual PIF form for all my raw materials or do other specification documents suffice ?

A The Product Information Form (PIF) has been developed to assist with the provision of information for the VITAL assessment however the information for VITAL can come from other sources such as raw material specifications or direct enquiry.

Q When companies won't provide me with full Raw Material specifications due to Intellectual Property (IP) issues, how should I consider this?

A To follow the VITAL process you will need to collect details about allergens – eg allergens added as an ingredient and details of cross contact allergens. When your supplier understands your requirements, you may be able to work with them to acquire the necessary information without breaching their IP requirements. If this is not possible, your HACCP team will need to discuss how to deal with this situation.

Q Do all my suppliers have to be VITAL compliant? Can I use numbers from the VITAL grid that correspond to the claims made by my suppliers?

A Suppliers need to have a good understanding of cross contact allergens at their plant so that you can use this information in your calculations – the AFGC's Product Information Form has been designed to assist with gathering information for VITAL however it is not mandatory to use this for VITAL. Your suppliers are encouraged to use VITAL to provide quantitative information however as VITAL is quite new this could be difficult, especially for international suppliers. In either case, as per all information you collect from suppliers, you need to have confidence in their data. If your supplier has an ingredient with a "May be present" claim then in order to use VITAL, you will need some quantitative assessment of the amount of total protein so that you can make a decision as to whether this allergen needs to be declared on the final product.