VITAL 2.0 – Q & A (v8, 17.05.2012)

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Introduction

This Q & A document is a supplement to the VITAL Q & A (also available on the Allergen Bureau website). It is intended to address questions specific to VITAL 2.0. New questions may be added to this document as required.

VITAL 2.0 Question Topics

Click to go directly to these topics

1. General Questions about VITAL 2.0

Q. How does VITAL 2.0 differ from the original VITAL?

A. VITAL 2.0 has new Action Levels. This means that products which have been assessed using VITAL (Version 1) may have different labelling outcomes when assessed using VITAL 2.0.

VITAL 2.0 has an interactive VITAL Action Level Grid which requires that Action Levels are calculated individually for each product. Also, VITAL 2.0 contains only two Action Levels (reduced from 3 Action Levels in the previous version of VITAL). Other changes include new definitions, new units of measure for gluten and clarification about allergen analytical testing, particulates and other aspects of the VITAL risk assessment.

VITAL 2.0 contains some important differences to the original VITAL and the 'Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) program' should be read to understand further how these changes will impact product(s) which have been assessed using VITAL (Version 1).

Q. What is wrong with the old version of VITAL? Does this mean that I may be selling potentially unsafe foods?

A. The VITAL Scientific Expert Panel examined the current levels in the VITAL Grid and they were considered appropriate and realistic values in terms of sensitivity within the allergic population based on the scientific evidence available when VITAL was originally developed. However, further clinical information is now available and this has been used to develop VITAL 2.0.

2. VITAL Scientific Expert Panel (VSEP)

Q. Has FSANZ seen the VSEP recommendations and do they accept them?

A. FSANZ has been engaged as a key stakeholder throughout the review process. They have also been provided with the preliminary report from the VSEP. FSANZ develops Food Standards but does not enforce food law and accordingly is not in a position to endorse VITAL.

Q. Will the Allergen Bureau continue to liaise with the VSEP?

A. Yes, the VSEP is now an integral part of the VITAL process and they will continue to be involved.

3. Transition to VITAL 2.0

Q. My company has multiple VITAL assessments and we do not have the resources to update them to the new format.

A. The application of VITAL 2.0 may mean that there are changes to labelling outcomes – it is not necessary to transfer VITAL assessments to the new calculator to determine these changes. The concentration of cross contact allergens in a product, determined using VITAL (Version 1), can be compared against the new VITAL Action Level Grid and this may be a less resource-intense method of transitioning to VITAL 2.0.

It should be noted that the units of measure for cross contact from gluten-containing cereals has changed from "mg gluten per kg" to "mg protein per kg" and this should be considered in the risk assessment before comparing gluten cross contact with the new VITAL Action Level Grid.

It is important to consider the information provided in the 'Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program' (The VITAL Guide) as there is more information and clarification about the VITAL procedure and new definitions, such as Reference Amount, which will be required to use VITAL 2.0.

Below is an example showing how information from the original VITAL calculator could be transitioned to VITAL 2.0.

Check VITAL (Version 1) calculator (or manually calculated information) to determine concentration of cross contact allergens.

GRAND TOTAL - RM & Processing Cross Contact, & Concentration / Dilution Impact *(As Consumed)*	Units	Milk	Egg	Soy	Fish	Peanut	Tree Nut	Sesame	Crustacea	Gluten
	ppm	0.0	0.0	15.1	0.0	0.1	0.0	8.9	0.0	0.0
	Labelling	*Must label*	*Must label*	*May be present: Soy*	*No Label*	*No Label*	*No Label*	*May be present: Sesame*	*No Label*	*Must label*

If the VITAL calculator was used, this information can be located on the "Summary" worksheet of the VITAL calculator (Row 85, as pictured above). In this example, the cross contact allergens are soy (15.1ppm – Action Level 2), peanut (0.1ppm – Action Level 1) and sesame (8.9ppm – Action Level 2). Gluten has not been identified as a cross contact allergen so it does not need to be considered for conversion to the new unit of measure.

Determine new Action Levels: To determine the relevant Action Levels, a Reference Amount or Serving Size must be set for this product. For more information on how to do this, refer to The VITAL Guide. In this example, the Reference Amount will be set at 50g and the VITAL Action Level Grid (incorporated into the VITAL Calculator) has been posted below.

VITAL
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VITAL Action Level Grid

Reference Amount / Serving Size ? 50 g

	Action Level 1	Action Level 2
Almond	<2 ppm	≥2 ppm
Brazil nut	<2 ppm	≥2 ppm
Cashew	<2 ppm	≥2 ppm
Hazelnuts	<2 ppm	≥2 ppm
Macadamia nut	<2 ppm	≥2 ppm
Pecan	<2 ppm	≥2 ppm
Pine nut	<2 ppm	≥2 ppm
Pistachio nut	<2 ppm	≥2 ppm
Walnut	<2 ppm	≥2 ppm
Wheat	<20 ppm	≥20 ppm
Rye	<20 ppm	≥20 ppm
Barley	<20 ppm	≥20 ppm
Oats	<20 ppm	≥20 ppm
Spelt	<20 ppm	≥20 ppm
Egg	<0.6 ppm	≥0.6 ppm
Crustacea	<20 ppm	≥20 ppm
Fish	<2 ppm	≥2 ppm
Milk	<2 ppm	≥2 ppm
Peanut	<4 ppm	≥4 ppm
Sesame seed	<4 ppm	≥4 ppm
Soy	<20 ppm	≥20 ppm
Lupin	<80 ppm	≥80 ppm
Mustard	<1 ppm	≥1 ppm

NOTE: **This Action Level Grid is specific to products with a Reference Amount or Serving Size of 50g. Do not use this Action Level Grid with your product – the VITAL Action Level Grid is interactive and must be determined specifically for each product.**

In this example, the cross contact concentration of soy protein is 15.1ppm which corresponds to Action Level 1. This is a different Action Level than was determined using VITAL (Version 1). The Action Levels for peanut and sesame remain unchanged.

Q. Will the original VITAL program cease to exist?

A The original VITAL will be phased out over the next few months and will no longer be supported after October 2012.

Q. How do you suggest that a business approach the transition from original VITAL to VITAL 2.0?

A. It is recommended that each business consider preparing a Transition Plan. This may include

- Understanding VITAL 2.0 – this could include training or other activities to understand the changes to VITAL 2.0. Reading the 'Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program' would be a good first step.

- Transitioning existing VITAL assessments to VITAL 2.0 - This may be done immediately or may be done as packaging/VITAL assessments come up for review or for new products. Any packaging changes due to changed labelling outcomes should also have impacts and timings considered in the Transition Plan.
- Plan for impact of changes – how will they be communicated? What are your customer(s) requirements with regard to transition to VITAL 2.0?

4. Ingredient Listings and "May be Present"

Q. VITAL 2.0 does not have Action Level 3 and there is no requirement for cross contact allergens, identified at high levels, to be included in the ingredient listing. This is different to VITAL (Version 1).

A. That is correct, VITAL 2.0 does not have an Action Level 3 and does not support labelling a cross contact allergen as an ingredient. Gross levels of cross contact should be addressed using GMP and/or the HACCP plan. The core message of VITAL is to eliminate and reduce cross contact allergens wherever possible.

Q. Will there potentially be less precautionary labelling statements used on products due to VITAL 2.0?

A. The objective of VITAL is to provide meaningful precautionary statements. VITAL 2.0 uses an interactive Action Level Grid so the Action Levels depend on the Reference Amount or Serving Size for the individual product. Some products may find increased requirement for precautionary statements and some will require reduced requirements for precautionary statements – it is not possible for the Allergen Bureau to predict whether there will be more or less precautionary statements. The focus of VITAL is on meaningful and consistent precautionary labelling.

5. VITAL 2.0 Calculator

Q. Can I still use the old calculator to perform new VITAL 2.0 assessments or do I need to only use the updated calculator?

A. You should start to use the VITAL 2.0 calculator to conduct VITAL risk assessments. The VITAL 2.0 calculator has been designed specifically to work with the new aspects of VITAL 2.0 such as the new VITAL Action Levels.

Q. Can I transition my data across or do I have to redo all the risk assessments on the new calculator?

A. There is no tool available to transition data to the new VITAL calculator. Information about how to transition to VITAL 2.0 is in the "Transition" section of this document.

Q. What types of reports will I be able to get from the VITAL 2.0 calculator?

A. The reports available include a detailed and summary report in pdf format which can be saved and shared (ie by email) separately to the VITAL Calculator file. The detailed report includes all information inputted into the calculator, including formulation information. The short summary includes labelling recommendations only.

Q. How are assumptions stored in the new VITAL Calculator?

A. The issue of absent or incomplete assumptions for the VITAL risk assessment has been reported to the Allergen Bureau. To try to assist with improving the quality of the recording of assumptions, further information about writing assumptions has been included in the 'Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program'. Further to this, there is space in the calculator to record assumptions during the risk assessment (rather than recording assumptions on a separate page). It is mandatory to include assumptions for each ingredient and assumptions regarding cross contact due to processing. There is also a place to add assumptions with regard to the dehydration or concentration factor used in the calculations.

Q. Will the Allergen Bureau be developing a migration tool to move data from the VITAL calculator to the VITAL 2.0 calculator?

A. No.

Q. Can I email the calculator or will I lose the imbedded calculations and macros?

A. We do not recommend emailing the calculator however, where required, it is best to "zip" the file prior to emailing.

6. VITAL Action Level Grid

Q. Is there still a VITAL Action Level Grid? Where will it be located?

A. The Action Level Grid is now imbedded in the VITAL 2.0 interactive calculator which can be downloaded from the Allergen Bureau website.

Q. My VITAL assessment has cross contact allergens identified at Action Level 3.

A. Check what the new labelling recommendations are for your product. An Action Level 3 may be either Action Level 1 or Action Level 2 using the new VITAL Action Level Grid.

Q. What should I do if I determine that I should have a precautionary statement on a product that I am currently selling?

A. Where there are more stringent labelling changes required, it may be necessary to prioritise these changes. Some VITAL users may perform VITAL as a requirement of their contract with a customer and in this case, they should consult with their customer. Complete the labelling change as soon as practicable. Seek legal advice if relevant.

7. Reference Dose

Q. What is the Reference Dose?

A. Reference Dose is the milligram protein level (total protein from an allergic food) below which only the most sensitive individuals (between 1% and 5% depending on the quality of the data set available) in the allergic population are likely to experience an adverse reaction. The Reference Dose is set by the VITAL Scientific Expert Panel and should only be changed on advice of the Allergen Bureau. The Reference Dose is used to calculate Action Levels.

8. Reference Amount or Serving Size

Q. Why is the term 'Reference Amount or Serving Size' used?

A. The term Reference Amount or Serving Size in the context of VITAL 2.0 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 determination of the Reference Amount or Serving

Size is a business decision. It is recommended that where serving size is used that the AFGC serving size principles should be applied.

The Reference Amount or Serving Size is inputted into the VITAL Action Level Grid to calculate the relevant Action Levels. The larger the Reference Amount or Serving Size, then the Action Levels become lower (and more conservative). An example where it may not be appropriate to use serving size from the Nutrition Information Panel is where there a range of the same product with different sizes (e.g. Snack Size and King Size chocolate bars). A Reference Amount may be chosen to standardize the Action Levels and hence the labelling recommendations across the range.

Q. I am a supplier of premixes and blended ingredients and I don't have a "Serving Size" for my products. How do I use VITAL 2.0?

A. There is an option in the calculator to proceed without nominating a Serving Size or Reference Amount. Provide your customer with information about any particulate cross contact allergens and the concentration of any readily dispersible cross contact allergens. Action Levels are not applicable to ingredients intended for further processing prior to presentation to a customer.

Q. I am an ingredient supplier and I would like to know whether the concentrations of cross contact allergens that I have been identified should be considered as low or high. How can I do this if I don't have a Reference Amount or Serving Size?

A. VITAL theory dictates that wherever cross contact is identified that it is reduced or eliminated – so, any ingredient should have the minimum possible concentration of cross contact allergen. The percentage of the ingredient used in a final product will determine the final concentration of cross contact in the finished product and the Reference Amount or Serving Size of the finished product will determine the Action Level and the labelling recommendation.

It is possible to run some scenarios to see if it is likely that the cross contact in the product would be likely to drive the use of a precautionary statement in the final product. Cross contact can also be incorporated due to other ingredients and during the manufacturing process.

To get the most conservative result assume that

- the ingredient will be used in the maximum possible amount in the finished product; and
- the Reference Amount or Serving Size will be maximum possible.

For example, wheat flour (ingredient) has soy cross contact at 100ppm. If this is typically applied at 30-60% of finished product, assume it is present at 60% which

would give (60% x 100ppm) 60ppm in the finished product. Use your knowledge of possible applications of this product to work out a Reference Amount or Serving Size. In this example, it may be conservative to use 100g which would be 2-3 pieces of bread. Action Level 2 for soy at 100g is ≥10ppm. In this example, 100ppm of soy cross contact in this ingredient would be likely to be an unacceptably high cross contact for your customer.

It should be noted that as an ingredient supplier, you should report the following to your customer

- the presence of any particulate cross contact allergen
- the concentration of any readily dispersible cross contact allergens

9. Gluten

Q. Why has the terminology and units changed for gluten? (Gluten containing cereals (mg total protein) rather than (mg gluten))?

A. The data used by the VITAL Scientific Expert Panel to report levels for gluten containing cereals was reported in mg total protein so this is the more appropriate unit of measure to use.

Q. How do I convert from mg gluten to mg protein - have you published conversion factors?

A. We are unable to provide conversion factors. Use information from the Nutrition Information Panel or food tables to determine the mg protein level from a gluten-containing cereal source.

10. Fish

Q. Why has the definition of fish changed? What do I do if I have cross contact from molluscs?

A. Finfish and molluscs are allergenically distinct so a Reference Dose for these foods should be considered separately. The data used to set the Reference Dose for fish is based on data from testing using finfish. There was not sufficient clinical data available to set a Reference Dose for molluscs. Further to this, the FSANZ Review of Regulatory Management of Food Allergens, December 2010 recommends that the definition of fish is clarified to reflect that fact that finfish and molluscs are allergenically distinct.

11. Tree Nuts

Q. Why has the definition of tree nuts changed?

A. The range of nuts for which there is data available is limited and we have adhered to the VSEP recommendation that we include only limited tree nuts in the VITAL 2.0 definition (almond, Brazil nut, cashew, hazelnuts, macadamia nut, pecan, pine nut, pistachio nut and walnut). Further to this, the FSANZ Review of Regulatory Management of Food Allergens, December 2010 recommends that the definition of tree nuts required for mandatory labelling be reviewed to include only those that are most relevant to food allergy.

12. Additional Allergens

Q. VITAL 2.0 has two new allergens listed, mustard and lupins – do I need to label for these in my "May be present" statement?

A. Lupin and mustard are not currently required to be labelled under the Australia New Zealand Food Standards Code Standard 1.2.3.

The VSEP was able to set a Reference Dose for lupin and mustard as there was sufficient clinical data available.

It is recommended that you consider the regulatory requirements for allergen labelling for the country where your product is sold and provide labelling information accordingly. For product sold in Australia and New Zealand, the Allergen Bureau does not recommend labelling for the presence of allergens other than those required for mandatory declaration.

Q. Did the VSEP make a recommendation for celery?

A. No, there was insufficient data to set a reference dose for celery.

13. Allergen Analysis

Q. What role does analysis play in the VITAL program?

A. The preferred method to identify and quantify cross contact allergens in a VITAL risk assessment is to sum the cross contact which is identified by the supplier in each raw material, with cross contact allergens identified during a physical audit of the production environment. However, there is a significant role of allergen analysis in:

- validation of the VITAL risk assessment;

- verifying ingredient allergen statements and potential raw material cross contact;
- targeted analysis of problem pieces of processing equipment;
- confirming assumptions made during the implementation of VITAL (such as validation of cleaning);
- testing allergen status of the final product to compare with calculated results from VITAL assessment which may be especially relevant to high risk environments; and,
- monitoring the effect of critical changes.

Further information about VITAL and allergen analysis is in the 'Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program'.

Q. What should I do where the levels of detection are greater than the Action Levels?

A. Allergen analysis should not be used to determine cross contact concentration. Allergen analysis may be used as a verification activity to confirm results from a risk assessment of ingredients and the processing environment however it is not expected that results from allergen analysis are compared directly with Action Levels.

14. Consumers and VITAL

Q. How do I communicate the changes to our consumers?

A. This is a business decision and will depend on any existing channels of communication (other than allergen information provided on the product label).

Q. How do I communicate to consumers that my product has undergone a VITAL 2.0 risk assessment when there is no requirement for a "may be present" statement.

A. The Allergen Bureau is working through options for improved communication with regard to VITAL for consumers. Options include using a VITAL logo and/or information in an extended labelling application delivered through smart phone technology. Some manufacturers choose to communicate about their use of VITAL through their website and/or consumer services.