# VITAL Auditor Guide (v2, 19.10.12)

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## Introduction

VITAL should be included in a food safety audit as part of the Allergen Management Plan. The information below has been prepared to provide some assistance in the key areas of VITAL however it is not meant to replace appropriate training in VITAL. This information may not be relevant to all manufacturing circumstances and is not meant to be an exhaustive list of areas which could be checked as part of an audit or to contradict an auditor's judgement as to the appropriateness of an Allergen Management Plan. Any VITAL assessment should be considered as part of overall the allergen management at a manufacturing site.

## Information to be considered when auditing a VITAL Assessment

| # | Audit Point | Comments |
|---|---|---|
| 1 | Cross contact allergens from raw materials | • Cross contact allergens can be identified from any trusted source such as specifications, the Product Information Form (PIF), correspondence with the supplier and the results from 2nd Party Approved Supplier program audits which have included cross contact allergens in the scope.<br>• Cross contact allergens should be correctly transferred to the VITAL calculator.<br>• Cross contact allergens should be differentiated as Particulate and Readily Dispersible as defined in the 'Food Industry Guide to the VITAL Program'<br>• Care should be taken that only cross contact allergens are considered using the VITAL process – intentionally added allergens, even when highly processed and/or added at small amounts, are required to be declared on the label by the Australia New Zealand Food Standards Code (ANZFSC).<br><br>**Key documents:** Formulations, information from ingredient suppliers (eg Product Information Form (PIF), specifications, correspondence, 2nd Party Audits etc), Detailed Summary Report from the VITAL Calculator. |
| 2 | Cross contact allergens from processing (line, people, tools) | • Cross contact allergens from processing should be identified by people who have a sufficient understanding of the engineering and production procedures.<br>• The rationale for presence or absence of cross contact due to processing should be recorded.<br>• Review operational practices and facility conditions to confirm that defined controls are in place/followed and no obvious cross contact risks observed that have not been considered by the manufacturer and/or included in the Assumptions.<br>• Appropriate Assumptions for product scheduling should be recorded.<br>• All incidental allergen contamination (line, people, tools) should be considered and |

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| | | relevant assumptions recorded.<br>• Assumptions should be filed appropriately within Quality system eg recorded in meeting minutes from a cross functional risk assessment for cross contact allergens.<br><br>**Key documents:** Quality documentation such as the Assumptions used to perform the VITAL assessment (in the detailed summary report from the VITAL Calculator) and/or meeting minutes or similar outlining the process and results of the identification of cross contact sources from processing, information about other allergen-containing products handled on site which could be a cross contact source. |
| 3 | Determination of total protein concentration from cross contact allergens | • The concentration of cross contact protein from an allergen source can be calculated either manually or using the most recent version of the VITAL calculator (refer to www.allergenbureau.net).<br>• Check that the data from raw material specifications and assumptions including variables such as scheduling to identify if the correct information has been used in the calculations.<br>• Production conditions which can affect the concentration of cross contact allergens in the final food should be recorded in the VITAL calculator or in another part of the quality system documentation.<br><br>**Key documents:** Detailed Summary Report from the VITAL Calculator |

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| 4 | Assumptions | • Appropriate assumptions including factors which prevent the inclusion of additional cross contact allergens to those identified in the VITAL Assessment. For example, production procedures, purchasing requirements (eg approved suppliers), cleaning procedures etc.<br>• Assumptions may be recorded on the Assumptions section of the VITAL calculator or in another part of the quality system documentation.<br>• Production procedures should be verified for compliance with the assumptions.<br><br>**Key documents:** Production Procedures including schedules, Quality documentation, Detailed Summary Report from the VITAL calculator and/or other appropriate section of the Quality documentation. |
| 5 | 'Reference Dose or Serving Size' | • Appropriate determination of whether a 'Reference Amount or Serving Size' is required.<br>-For products that are assessed to be an ingredient (ie. further processed before being sold to a retail customer): 'Reference Amount or Serving Size' is not relevant and the following information should be supplied to the customer:<br>(1) the presence of any particulate cross contact and<br>(2) the concentration of any readily dispersible allergen.<br>Action Levels and/or ingredient labeling is not relevant to ingredients which will be further processed .<br><br>-For product which are assessed to be a finished product (ie. Not further processed before being sold to a retail customer): determine the appropriate Reference Amount or Serving Size. Note that the largest Reference Amount or Serving Size should be used as it will calculate the more conservative Action Levels. Refer to the Definitions section of the Food Industry Guide to the VITAL |

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| | | Program for further information on setting Reference Amount or Serving Size.<br><br>**Key documents:** Detailed or Summary Report from the VITAL Calculator. |
| 6 | Ingredient Listing, Summary Statement and Precautionary Statement | For product for which a retail label is relevant:<br>• Results from VITAL calculations and/or manual calculations are to be transferred correctly to the food label.<br>• VITAL recommends the labelling format from the AFGC Food Industry Guide to Allergen Management and Labelling. Where a precautionary statement is required, the only statement that can be used with VITAL is “May be Present: Allergen”.<br>• The precautionary statement can only be used when the allergen is sporadic, unavoidable and has been documented using VITAL.<br>• Precautionary statements not to be used as a substitute for GMP or to address gross contamination.<br><br>**Key documents:** Detailed or Short Summary Report from the VITAL Calculator VITAL assessment, current labels. |
| 7 | Review of VITAL | • There should be a procedure in place for review of VITAL. This could be incorporated into a review of the Quality System.<br>• VITAL should be reviewed if there are any adverse reactions suffered by consumers due to consuming the food or if any assumptions change.<br><br>**Key documents:** details for requirement for review of VITAL and if performed, evidence that cross contact allergens, assumptions and other factors affecting the VITAL review have been reviewed. |