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Voluntary Incidental Trace Allergen Labelling (VITAL) Auditor Guide

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.

#	Audit Point	Comments
1	Cross contact allergens from raw materials	<ul style="list-style-type: none">• Cross contact allergens can be identified from any trusted source eg specifications, Product Information Form (PIF), correspondence with supplier (eg email), results from 2nd Party Approved Supplier program audits which have included cross contact allergens in the scope etc.• Cross contact allergens should be correctly transferred to the VITAL calculator or manual calculations.• Cross contact allergens should be differentiated as Particulate and Readily Dispersible. Refer to VITAL decision tree to ensure that Particulate and Readily Dispersible allergens have the correct labelling recommendations.• 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 (ANZFS Code). <p>Key documents: Formulations, information from ingredient suppliers (eg PIF, specification, correspondence, 2nd Party Audits etc), VITAL Calculator or manual calculations.</p>

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2	Cross contact allergens from processing (line, people, tools)	<ul style="list-style-type: none"> • Cross contact allergens from processing should be identified by people who have a sufficient understanding of the engineering and production procedures. • The rationale for any cross contact from a previous product should be recorded. • Review operational practices and facility conditions to confirm that defined controls are in place/followed and no obvious cross contamination risks observed that have not been considered by the manufacturer and/or included in the Assumptions. • Appropriate assumptions for product scheduling should be recorded. • All incidental allergen contamination (line, people, tools) should be considered and relevant assumptions recorded. • Assumptions should be filed appropriately within Quality system eg recorded in minutes from a cross functional quality meeting. <p>Key documents: Quality documentation such as the assumptions page of 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.</p>
3	Determination of total protein concentration from cross contact allergens	<ul style="list-style-type: none"> • 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). • Check that the data from raw material specifications and assumptions including variables such scheduling to identify if the correct information has been used in the calculations. • Production conditions which can affect the concentration of cross contact allergens in the final food, such as batch size, should be recorded on the Assumptions worksheet of the VITAL calculator or in another part of the quality system documentation. <p>Key documents: Assumptions, VITAL Calculator and/manual calculations.</p>



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4	Assumptions	<ul style="list-style-type: none"> • Appropriate assumptions include 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. • Assumptions may be recorded on the Assumptions worksheet of the VITAL calculator or in another part of the quality system documentation. • Production procedures should be verified for compliance with the assumptions. <p>Key documents: Production Procedures including schedules, Quality documentation, Assumptions page of the VITAL calculator and/or other appropriate section of the Quality documentation.</p>
5	VITAL grid	<ul style="list-style-type: none"> • Where manual calculations have been used, the most recent version VITAL grid should be used (refer to www.allergenbureau.net). <p>Key documents: VITAL Grid, manual calculations.</p>
6	Labelling statement	<ul style="list-style-type: none"> • Results from VITAL calculations and/or manual calculations are to be transferred correctly to ingredient statement of the food label as per the VITAL Decision Tree. • VITAL recommends the labelling format from the Food Industry Guide to Allergen Management and Labelling – 2007 Revised Edition. Where a precautionary statement is required, the only statement that can be used with VITAL is “May be Present: Allergen”. • The precautionary statement can only be used when the allergen is sporadic, unavoidable and has been documented using VITAL. <p>Key documents: VITAL assessment, current labels.</p>



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7	Review of VITAL	<ul style="list-style-type: none">• There should be a procedure in place for review of VITAL. This could be incorporated into a review of the Quality System.• VITAL should be reviewed if there are any adverse reactions suffered by consumers due to consuming the food or if any assumptions change. <p>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.</p>
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