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VITAL Review – What you need to know





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Important Notice (24 October 2011)

This document has been created to support communication activities about the VITAL Scientific Expert Panel (VSEP) Report as well as providing an overview of the impacts the VSEP report will have on the updated release of VITAL 2.0. A summarised version of the VSEP report is available on the Allergen Bureau website. The material provided in this summary is for information purposes only, it is not complete and should not be relied upon to conduct any part of an allergen risk assessment.

VITAL Review – What you need to know

What has been Happening

In 2010 the Allergen Bureau initiated a review of VITAL building on a commitment to continue to invest in VITAL to ensure that it remains a relevant tool for industry, following its successful launch in 2007.

The scope of the review included:

- ➔ Reviewing science that underpins VITAL;
- ➔ VITAL Action Levels within the VITAL Grid;
- ➔ The VITAL Procedure; and
- ➔ The VITAL Calculator

The updated version of VITAL will be known as VITAL 2.0 and is due to be released at the end of November 2011. VITAL 2.0 will supersede the original versions of the VITAL Grid, VITAL Procedure, VITAL Calculator and other VITAL resources.

Reviewing the Science – Why it is Important

The Allergen Bureau recognised a need to form a scientific expert panel (known as the VITAL Scientific Expert Panel VSEP) to review the underpinning science around food allergen thresholds. The scientific review was a critical body of work to ensure that the action levels set protect the allergic consumer by enabling industry to make appropriate precautionary labelling decisions and providing clear and consistent consumer communication through the use (or not) of the “may be present” statement.

The VITAL Scientific Expert Panel (VSEP) – Who are they?

The VITAL Scientific Expert Panel consists of international scientists specialising in allergen management, food allergy and risk assessment.

The VSEP is a collaboration between the Allergen Bureau, Food Allergy Research & Resource Program (FARRP) of the University of Nebraska & the Netherlands Organisation for Applied Scientific Research (TNO).

Members of the Panel:

- ➔ Steve Taylor (FARRP, Chair of the Panel),
- ➔ Joseph Baumert (FARRP),
- ➔ Rene Crevel (Unilever),
- ➔ Geert Houben (TNO),
- ➔ Simon Brooke Taylor (Allergen Bureau Consultant),
- ➔ Katie Allen (Paediatric Allergist Australia).

The Panel was assisted by Ben Remington (FARRP), Astrid Kruizinga (TNO), Ellen Dutman (TNO) and Harrie Buist (TNO).

The VSEP produced a report which sets out the work that they have conducted and their findings and recommendations. The full report will be available in due course on the Allergen Bureau website.

The VITAL Scientific Review – What are the main impacts?

The expertise within the group has meant that the outcome of the VSEP review is a robust and internationally relevant scientific review. This means that VITAL is based on the most current allergen science available and will ensure it remains an ongoing sustainable risk assessment tool.

- ➔ New Definitions -There are new terms that are relevant to the use of VITAL 2.0. New definitions for reference dose and reference amount or serving size have been introduced. Both the reference dose and reference amount and serving size are important and are required to determine the appropriate action level (ppm concentration) for a specific product to trigger (or not) a precautionary labelling decision.
 - ➔ Reference dose – The mg protein level (total protein from an allergenic 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.
 - ➔ Reference Amount/Serving Size – The Reference amount is defined as the maximum amount of the 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.
- ➔ Action levels are changing – The reference dose (mg protein level of allergen) information has changed from the original version of VITAL and is provided in the updated VITAL 2.0 grid.
- ➔ Gluten Representation- The units for measuring gluten cross contact have changed from mg gluten per kilogram to mg total protein from gluten containing cereals per kilogram. The action level for gluten-containing cereals will vary depending on the reference amount/serving size except where it is greater than 20ppm protein from gluten containing cereals. In this case it will be locked at 20ppm protein from gluten containing cereals to ensure that protection for both the wheat allergic and coeliac populations are considered.
- ➔ Allergens of International Interest – There is now sufficient information to set action levels for mustard and lupin and reference doses for these foods have been included. This information may be used to fulfil export requirements or if VITAL is used outside Australia or New Zealand. The Allergen Bureau currently does not recommend that products sold in Australia and New Zealand label for allergens other than those for which there is a mandatory requirement under Standard 1.2.3, Australia New Zealand Food Standards Code.

VITAL 2.0 – What will the updated Program look like?

- ➔ Quantification of Cross Contact – the assessment process to gather data about the impact of cross contact from ingredients and processing remains the same.
- ➔ An Interactive Action Level Grid – There will no longer be a 3 level VITAL Grid. VITAL 2.0 includes an interactive grid that determines the action level concentration via the relationship of reference dose for each allergen and reference amount/serving size. If your risk assessment determination provides a level that is equal to or above the action level then precautionary labelling is advised if it is below then no precautionary labelling is required.

- ➔ There will be no action level 3 triggering ingredient labelling – The original version of VITAL had an action level three where cross contact is considered significant and would trigger ingredient labelling. Manufacturers are encouraged to adhere to the principles of Good Manufacturing Practice (GMP) and eliminate or reduce cross contact where possible. It is a manufacturer's responsibility to manage the production environment and eliminate allergen hazards or impacts.
- ➔ VITAL Procedure – The VITAL Procedure will still exist however it will be as part of an overall VITAL Guidance document.
- ➔ VITAL Calculator – the VITAL Calculator will have an updated look and will allow risk assessment scenarios to be saved and updated as appropriate.
- ➔ Frequently asked Questions – To support VITAL 2.0 users and help troubleshoot where needed, information provided through interaction with VITAL users will be utilised to inform and develop the FAQ's.

Food Industry Stakeholders – What Happens Next?

Once VITAL 2.0 becomes available you will need to consider how your Business transitions to the updated program.

How do I learn more about VITAL 2.0?

Information forums are going to be held during November in Sydney on the 17th, Melbourne on the 22nd and Auckland on the 23rd. This is a great opportunity for industry to hear about the evolution of VITAL and the exciting next chapter with the launch of VITAL 2.0.

The VITAL 2.0 Guidance Document, Procedure & Calculator – the pilot phase

The Allergen Bureau is supporting a pilot phase to ensure all stakeholders will be able to experience the VITAL Guidance document, new procedure and calculator and provide input and feedback before VITAL 2.0 goes live.

When will VITAL 2.0 go Live?

It is anticipated that the 'go live' date will be at the beginning of February 2012. Between the period of December 2011 and the end of January 2012 the Allergen Bureau will be seeking feedback and creative solutions or ideas for change from industry. The focus of the feedback should be around the functioning of the calculator or additions or amendments to the Guidance document and procedure. (Please note: The reference dose information reported by the VSEP will not change)

The Food Allergic Community – What you need to know?

The Allergen Bureau continues to invest and support VITAL implementation and will support the food industry to transition products over time to VITAL 2.0. The VITAL risk assessment program is a robust scientifically sound approach to ensure industry make consistent precautionary labelling decisions which help inform the allergic consumer.

It will however continue to be important for allergic consumers to liaise specifically with individual Businesses to determine the status of VITAL 2.0 implementation and seek information on cross contact labelling.

Important Notice

The information provided in this summary is for information purposes only and is not complete and should not be relied upon to conduct any part of an allergen risk assessment. It corresponds to the updated VITAL 2.0 system (available end of November 2011). The updated VITAL 2.0 program will allow you to use the updated information in order to determine if a precautionary labelling statement is required by guiding you through the important steps when undertaking a thorough allergen risk assessment.

For more information about VITAL 2.0 you can attend an information session during November, or see the Allergen Bureau website for details: **www.allergенbureau.net/vital**.



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