



GUIDANCE TO AUSTRALIA/NEW ZEALAND FOOD INDUSTRY ALLERGEN RISK REVIEW ANOMALY FOR DARK CHOCOLATE

This industry guidance is not intended to be binding nor to represent legal advice from any of the parties that have engaged or collaborated in its development.

This guidance to the food industry, together with education and associated activities, is designed to improve the nature and consistency of allergen information provided to consumers where a dark chocolate allergen risk review anomaly occurs.

An allergen risk review anomaly (RRA), in relation to dark chocolate, and inconsistent labelling practices were identified by the confectionery industry. This occurs where dark chocolate is manufactured following production of milk chocolate, ie milk remains in the dark chocolate at variable levels, often above the Allergen Bureau Voluntary Incidental Trace Allergen Labelling (VITAL[®]) Program Action Level where precautionary allergen labelling (PAL) would be recommended. This is also above the allergic consumer and their carer's expectation of 'trace' or 'minimal' (cow's) milk levels.

BACKGROUND

The Australian Industry Group (Ai Group) Technical Committee established a working group (the working group) with the Allergen Bureau (AB) and, in consultation with the Australian Food & Grocery Council (AFGC), worked together to consider industry guidance in relation to this allergen risk review anomaly and food labelling.

A jurisdiction consensus was sought to determine the best way to manage the issue.

The Ai Group working group led discussions with the NSW Food Authority (NSWFA), Food Standards Australia New Zealand (FSANZ) and Implementation Sub-Committee for Food Regulation (ISFR) on how best to manage the risk. ISFR members include Australian Government, New Zealand Government and Australian state and territory authorities responsible for food regulation. Each jurisdiction enforces their respective Food Acts that give legal effect to the Australia New Zealand Food Standards Code (the Code).

The Code requires the mandatory declaration of certain substances or foods when present as an ingredient, sub-ingredient, additive or processing aid (Food Standards Code – *Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations. Clause 4*). However, the Code does not define an 'ingredient' (the definition of an ingredient was removed with the last Code Revision) and is silent on the labelling of allergens present in other circumstances, for example where due to cross contact (cross contamination).

THE ISSUE

The issue of milk in dark chocolate has been identified as an allergen risk review anomaly, in commercial operations, where the allergen is not an intended ingredient nor is it included as part of the recipe as an ingredient, sub-ingredient, additive or processing aid in the product. It falls outside the mandatory

labelling requirements in *Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations* of the Code and does not necessarily fit with the principles of best practice risk review and PAL.

A common example is where milk from milk chocolate manufacture remains within the processing line in subsequent manufacture of dark chocolate made on the same production line. The presence of milk is unavoidable in a normal manufacturing environment. A complete shut down and clean to remove the allergen is impractical, due to the potential for microbial growth and process issues through the introduction of water into a chocolate system. Alternatively, continuous flushing to remove milk traces is not viable, due to excessive product waste and downtime. Other solutions identified through HACCP, such as duplicating production lines, may not be commercially practical or achievable either.

As such, this unintended allergen substance represents a food safety allergen anomaly.

In these circumstances, milk allergen in the dark chocolate is unavoidably present, potentially at higher and significant levels than is considered appropriate under current risk review approaches. Its presence is predictable and known and cannot be eliminated or minimised sufficiently, despite good manufacturing practice (GMP) and the commercial practicality of implementing HACCP.

Consequently, there may be significant carry forward of milk allergenic proteins in the initial manufacture of a product due to the difficulty and impracticability of removing the protein during GMP cleaning processes. For example, the amount of milk protein in the dark chocolate can initially be quite high and will diminish throughout production, until it potentially falls below the limit of detection.

Voluntary PAL statements are typically used by industry to indicate allergens that ‘may be present’ in a food, where they are not part of the product recipe. This is in line with industry guidance for cross contact allergen risk review and communication and is consistent with the application of the Allergen Bureau (AB) VITAL® Program. Given the combination of factors, PAL may not be sufficient to safe guard the allergic consumer (additionally there is evidence that consumers place less reliance on the PAL than they do of the ingredient statement) and so including the allergenic substance, ie milk as the last ingredient in the ingredient list of the dark chocolate is considered as potential industry best practice.

Given this approach is a departure from current management and labelling practices, the working group with the expert guidance of the AB (in consultation with the Allergy & Anaphylaxis Australia (A&AA), Allergen New Zealand and AFGC) sought ISFR’s assistance in developing a bi-national (Australia and New Zealand) consensus between government regulators as to how this issue could be best managed to ensure consumer protection.

ISFR considered the issue in August 2017 and advised that:

- ***“no concern was raised by any jurisdiction”*** with regard to ***“listing milk at the end of an ingredient list on a dark chocolate”***, in these circumstances
- it would ***“also accept the alternative proposal to list an advisory statement to alert the allergic consumer to the potential presence of traces of milk in dark chocolate”***.

ISFR also advised that:

“it is for food businesses themselves to identify the most appropriate labelling solution for their product in the circumstances. This could be achieved by undertaking a specific risk assessment for each affected product and should align with best industry practice”.

Current industry best practice is considered to consist of:

- i) allergen risk review as described in the *Allergen Bureau ‘Allergen Risk Review’ interactive website* <https://info.allergenbureau.net/>
- ii) application of the *VITAL® Program* in conjunction with HACCP and GMP;
- iii) allergen labelling as described in the *VITAL® Best Practice Labelling Guide for Australia and New Zealand*;
- iv) *Food Industry Guide to Allergen Management and Labelling*; and

v) where applicable, this *Guidance to Australia/New Zealand Food Industry on Allergen Risk Review Anomaly for Dark chocolate*.

KEY GUIDING PRINCIPLES

To facilitate industry consistency and education, the working group has developed the following key guiding principles (KGP) and decision tree (DT), in conjunction with GMP standards and HACCP, as part of the allergen risk review anomaly industry guidance.

GMP standards and practices are key for managing and controlling allergen cross contact.

Our guidance is that these specific risk communication labelling practices must only be utilised when an allergen risk review anomaly has been identified, and the KGPs have been applied.

Where the KGPs occur (all three), this guidance recommends, including the allergenic substance, ie milk as the last ingredient in the ingredient list of dark chocolate.

Principle:	Rationale
<p><u>Principle 1</u> Where a dedicated manufacturing line or plant cannot be commissioned to manage the allergen risk review anomaly, and</p>	<ul style="list-style-type: none"> - Australia and New Zealand are both relatively small markets with many operators do not have the capacity for multiple factories, dedicated lines or ability to isolate production associated with allergen and non-allergen containing food processing
<p><u>Principle 2</u> Where review or changes to GMP will not impact the management of the allergen risk review anomaly, and/or Where the manufacturing process is a closed system and cannot be cleaned or flushed sufficiently to support PAL, and</p>	<ul style="list-style-type: none"> - Scheduling and production flows does not eliminate the allergen anomaly - Cleaning accessible areas and piping does not remove the allergen - Holding tanks, conches, pipes, and coating machinery retain allergens (milk) from the previous production and cannot be practically and sufficiently cleaned
<p><u>Principle 3</u> When the allergens are going to be present in a product at variable levels, sometimes elevated above Action Level 2 (as per VITAL[®]) or above a level that triggers PAL</p>	<ul style="list-style-type: none"> - For consumer protection, the guidance recommends labelling the allergen (milk) as the last item in the ingredient list, so as to appropriately alert the allergic consumer

Note: A record of the cross contact impact should be documented on the master recipe to indicate the inclusion of the allergen within the ingredient list. This may involve supplier documentation, eg product specifications, Product Information Forms (PIFs) which capture information about production systems, shared equipment usage and quantitative analysis whereby the user can determine appropriate allergen labelling for their retail product.

Note: Declaring the allergen substance, ie milk, as the last ingredient in the ingredient list is not a substitute for appropriate risk review. Every attempt should be made to eliminate the allergen effectively.

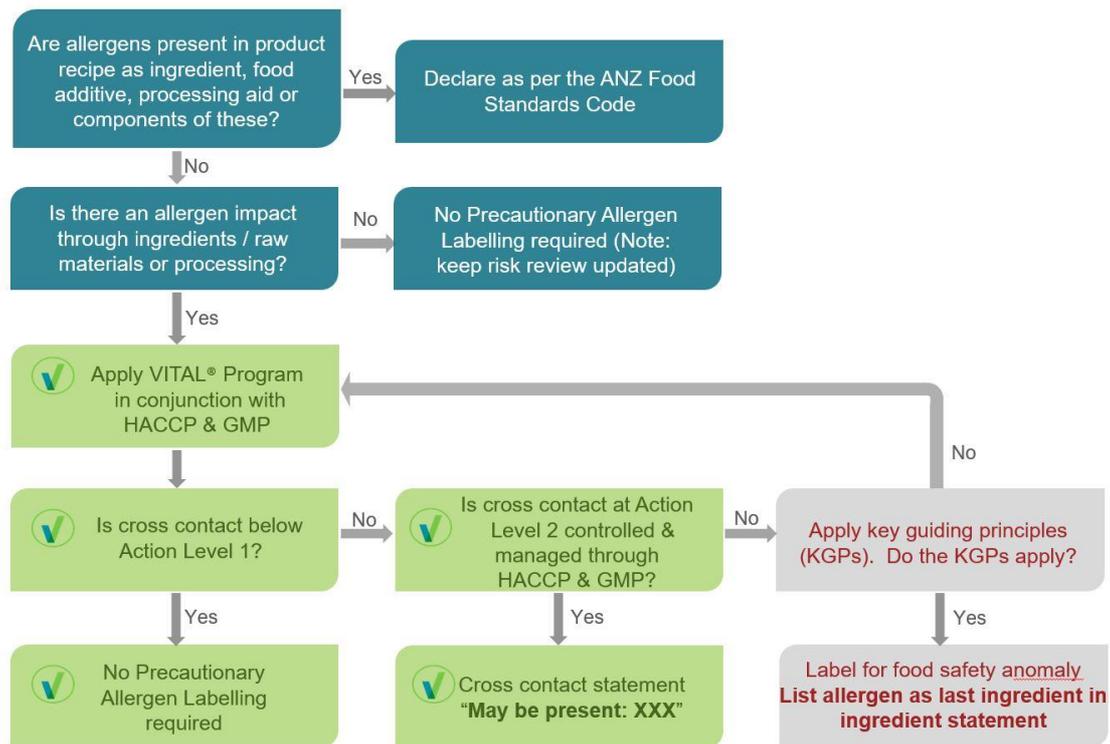
Note: Verification of the risk review anomaly should be supported with documentation on the frequency of occurrence, to demonstrate duty of care and to ensure compliance with Australian Consumer Law requirements regarding accuracy of labelling.

Note: The approach to declare the allergen risk review anomaly in the ingredient list has the support of the Australia and New Zealand consumer allergen groups - Allergy & Anaphylaxis Australia (A&AA) and Allergy New Zealand (Allergy NZ).

Note: Other issues include consideration of independent legal advice, import/export criteria and labelling, industrial supplier product labelling and retail product packaging/labelling differentiation.

DECISION TREE

This decision tree is a diagrammatic approach to validating an allergen risk review anomaly, in conjunction with GMP standards, HACCP and KGPs, to facilitate labelling consistency and assist the cow's milk allergic consumer.



SUMMARY

This allergen risk review anomaly for dark chocolate guidance was initiated by the confectionery industry as a response to the improved understanding of unintended occurrence and allergen risk in manufacturer.

The approach proposed is the result of extensive industry consideration, collaboration and communication with regulatory setting and enforcement agencies and the allergenic community key stakeholders. It is designed as industry guidance to achieve allergen management and labelling consistency and, most importantly, to adequately inform and protect the allergen consumer by putting consumer safety and industry's duty of care foremost.

However, it is not, a substitute for GMP, HACCP or allergy risk review assessment.

This industry guidance is not intended to be binding nor to represent legal advice from any of the parties that have engaged or collaborated in its development, namely the following:

- The Australian Industry Group (Ai Group)
- The Allergen Bureau (AB)
- The Australian Food and Grocery Council (AFGC)

- Implementation Sub-Committee for Food Regulation (ISFR)
- Food Standards Australia New Zealand (FSANZ)
- New South Wales Food Authority (NSWFA)
- Allergy & Anaphylaxis Australia (A&AA)
- Allergy New Zealand

As noted by ISFR ...

“... it is for food businesses themselves to identify the most appropriate labelling solution for their product and circumstances.”

It is intended that this guidance provides current best industry practice and additionally forms part of broader industry education and will be incorporated into Allergen Bureau resources, including the Allergen Bureau ‘Allergen Risk Review’ interactive website; the VITAL® Program; and the *Food Industry Guide to Allergen Management and Labelling*.

Communication with the key allergen agencies in Australia and New Zealand is continuing to support consumer education activities.

FOR FURTHER INFORMATION:

Ai Group (Confectionery Sector) - Technical & Regulatory Manager by telephone 03 9867 0181 or email jennifer.thompson@aigroup.com.au

Allergen Bureau - from Australia: 0437 918 959; for international calls: + 61 437 918 959 or email info@allergenbureau.net. Website: www.allergenbureau.net.

AFGC - <https://www.afgc.org.au/our-expertise/health-nutrition-and-scientific-affairs/labelling/>

Allergy & Anaphylaxis Australia (A&AA) - telephone 02 9680 2999 or email msaid@allergyfacts.org.au

Allergy New Zealand - telephone +64 9 623 3912 or email allergy@allergy.org.nz

Food Standards Australia New Zealand - <http://www.foodstandards.gov.au/consumer/foodallergies/Pages/default.aspx>

NSW Food Authority - <http://www.foodauthority.nsw.gov.au/foodsafetyandyou/food-labelling/labels-and-the-law/declaring-allergens>