



VITAL Q&A: LEGAL CONSIDERATIONS

How does VITAL relate to the Food Standards Code?

Clause 4 of Standard 1.3.2 of the Australia New Zealand Food Standards Code requires the declaration of allergens where intentionally present in the food, as an ingredient, sub-ingredient, additive or processing aid. It is a legally enforceable mandatory standard, and contravention can result in prosecution or other government enforcement measures.

VITAL, on the other hand, relates to the non-intentional, or incidental, presence of the allergen in the food, for example through common handling or processing. It is not a mandatory standard, but rather a tool developed by the food industry itself to better manage the hazard posed by the incidental presence of trace amounts of allergens, and so better protect consumers. Its use is voluntary, although greatly encouraged.

There is no overlap or conflict between Standard 1.2.3 and VITAL. If an allergen is present in a food as an ingredient, additive, processing aid, or a component of any of these, then Standard 1.2.3 applies. VITAL starts where Standard 1.2.3 finishes to deal with the risk management of allergens that are present incidentally rather than intentionally.

Does VITAL labelling contravene any law?

No. Clause 12 of Standard 1.1.1 of the Australia New Zealand Food Standards Code permits mandatory statements, such as the ingredients list (Standard 1.2.4) or allergen declaration (Standard 1.2.3), to include words which modify that statement provided that the additional words do not contradict, or detract from the intended effect of, the mandatory statement.

A declaration of allergens over and above that required by food standards does not contradict or detract from the mandatory statements, and so is permitted.

PO Box 700
Cherrybrook NSW 2126

Phone +612/(02) 8850 5775
Fax +612/(02) 8850 5778
<http://www.legalfinesse.com>

Does VITAL replace Standard 1.2.3?

No. VITAL must not be used where the allergen is present intentionally, as an ingredient, component, additive or processing aid. In such cases, the allergen must be declared in accordance with Standard 1.2.3 of the Australia New Zealand Food Standards Code even if present at less than any action threshold set out in VITAL.

VITAL only applies to allergens that are present through incidental transference, it does not apply to allergens present as a result of deliberate addition of a food ingredient, additive or processing aid.

Has FSANZ approved VITAL?

No. Food Standards Australia New Zealand has responsibility to develop food regulatory measures, such as food standards, where necessary to protect public health and safety. Its standards are mandatory and have the force of law. It has addressed the issue of allergens, to the extent that it considers appropriate to do so, in Standard 1.2.3 of the Australia New Zealand Food Standards Code.

VITAL was developed by the industry to go further than Standard 1.2.3 requires, but on a voluntary rather than mandatory basis. FSANZ does not give approvals for voluntary industry codes, and no approval has been sought.

FSANZ, along with other stakeholders such as Anaphalaxis Australia (the association for people with food allergy and intolerance and their families), was invited to participate in the development of the VITAL tool, but this should not be understood to suggest that FSANZ endorses or has approved the tool.

What legal protection does VITAL offer?

While the use of VITAL in itself offers no direct legal protection, it does provide the evidentiary basis to establish that a manufacturer has taken due care and skill in marketing the product. The proper implementation and use of VITAL is evidence that a company has used best practice in trying to manage the risks associated with incidental trace allergens.

Whether or not a company has used such endeavours is often the basis to establish a defence, or at least mitigation, in product liability actions. It can be used, for example, to show that goods (produced in accordance with the VITAL tool) are of merchantable quality, or have the degree of safety that persons generally are entitled to expect, and

that the manufacturer has conducted due diligence and met reasonable standards of care in marketing the product, and so forth.

Why does VITAL allow some allergens to be present without labelling?

"Green" action levels reflect a scientific review of allergen incident literature in relation to levels that are unlikely to trigger reactions in most of the sensitive population. On balance, most of the sensitive population could consume the food with very little risk, and to effectively warn against consumption through an allergen declaration would both overstate the risk and deny food choice to a group that already suffers a highly restricted diet compared to the non-sensitive population.

VITAL is a risk management tool, not a risk elimination tool. There is always some degree of risk that a consumer can suffer some idiosyncratic reaction to a food, and not every risk can or should be labelled or warned against. VITAL seeks to provide the sensitive population with usable information rather than warn against every possible contingency, no matter how remote.

How should VITAL be audited?

VITAL is a risk management tool that can, and should, be audited in the same manner as any other risk management tool, using documentation, records and process inspections.

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Chris Preston
Principal
Email: chris.preston@legalfinesse.com
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