

Legal aspects of VITAL Grid

With 17 million Europeans, including 600,000 Dutchmen, who suffer from one or even multiple food allergies, a good allergen management system in the food industry is of vital importance. In this respect, there is also a great need for clarity regarding the mentioning of possible cross-contamination (unintended presence) of allergens on food labels.

The Voluntary Incidental Trace Allergen Labelling (VITAL Grid) system was introduced in Australia in 2007. It operates with threshold values for allergens, thus providing greater clarity to consumers and manufacturers. VITAL Grid enables the risk assessment of cross-contamination with allergens. Depending on the outcome, a precautionary statement ('may contain' or 'may be present ') can be placed on the packaging, or there may be an accepted risk for which no warning is needed.

The VITAL Grid system today enjoys broad support in the Dutch food industry as a tool for mentioning possible cross-contamination on food labels. The question is whether this system also provides the desired clarity on the liability of the manufacturer for cross-contamination.

Manufacturer's liability

In principle, the manufacturer has no legal obligation to mention the risk of cross-contamination on food labels. Only if allergens are used as an ingredient the mentioning on the label is compulsory. Also the new Regulation on the provision of food information to consumers (Regulation (EU) No 1169/2011) does not prescribe the mentioning of the risk of cross-contamination. The new Regulation - which enters into force on 13 December 2014 - requires that voluntary additional information or warnings, such as the 'may contain' labelling, may not be misleading, ambiguous or confusing on any account, and that such information shall be based on relevant scientific data.

Despite the fact that manufacturers are not obliged to mention the risk of cross-contamination, manufacturers could still be held liable for unintended presence of allergens. For, under certain conditions, this could result in an unlawful act (if the manufacturer has taken insufficient care), or manufacturers may be held liable for product liability (where it briefly concerns the safety expectations of the consumer). Unlike in the case of an unlawful act, it is not required for product liability that the manufacturer can be blamed.

In respect of both liability grounds the manufacturer must prove that he has made every effort to avoid cross-contamination as well as any unexpected allergic reaction that arose therefrom. In this respect it comes down to whether the manufacturer - if not too problematic given the time, effort and potential costs – has taken appropriate precautions to avoid cross-contamination. This may include measures concerning *inter alia* recipe management, cleaning, storage, transport, rework and layout of spaces and equipment.

In addition, it is important to be aware whether manufacturers should have warned about the risk of cross-contamination. Whether a warning is mandatory and whether the warning mentioned is adequate depends on a number of circumstances, such as the degree of foreseeability of careless behaviour of the consumer, whether the danger is known to the manufacturer as well as the consumer's safety expectations. Finally the inconvenience of the precautionary measures that need to be taken plays a role too.



Excessive warnings

It will be clear that if a risk of cross-contamination exists, manufacturers would be well advised to mention a warning on its product. For this reason, manufacturers tend to include a warning out of precautionary considerations.

This, however, has the adverse effect of using excessive warnings, which leads to allergic consumers being unnecessarily restricted in their choice of food products. In addition, the warning loses its information value because as a result of frequent confrontation with warnings the consumer cannot assess whether the risk is real.

Providing clarity

VITAL Grid could provide a balance between the avoidance and reduction of incidents, and the unnecessary and undesired warnings for cross-contamination. The system offers a tool for mapping and reducing the risk of cross-contamination and provides both manufacturers and consumers with insight into the risk of cross-contamination by using thresholds. The application of the VITAL Grid system will possibly also meet the requirements that the new Regulation sets to information on a voluntary basis (i.e. that the information is not misleading, ambiguous or confusing). It should be observed though that for the VITAL Grid system to provide the desired clarity to consumers and manufacturers and to contribute to the exclusion of the manufacturer's liability it should particularly be applied all across the industry and the allergic consumer should be familiar with the VITAL Grid system and the associated thresholds. In addition, to provide more legal certainty to manufacturers, the VITAL Grid system could be laid down by law.

No guarantee

Although the VITAL Grid system can provide the allergic consumer with much more guidance compared with the current 'may contain' labelling without thresholds, the application of VITAL Grid does not furnish the manufacturer - especially seeing the lack of a legal basis - with any guarantee that he cannot be held liable for an unexpected allergic reaction. VITAL Grid is a risk *management* and not a risk *elimination* tool and does therefore not offer complete safety with regard to the presence of allergens.

However, the use of the VITAL Grid system indicates that manufacturers have at any rate exercised great care in the risk analysis of cross-contamination, as well as regarding the risk

information to allergic consumers. This is relevant to the question whether manufacturers can be held liable.