EUROPEAN ASSOCIATION OF
FRUIT AND VEGETABLE PROCESSORS

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TRANSFORMATRICES DE FRUITS ET LÉGUMES

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**Precautionary Allergen Labelling (PAL)**
**and the effects for the fruit and vegetable processing industry**

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## Introduction

"*The Dutch delegation raised the issue of non-homogeneous contamination that can occur for example with the harvest of lentils where some grains can be also harvested (because the soil was used the previous year for wheat). This creates confusion regarding the labelling of allergens. FDE recommends adopting the VITAL guidelines in this context, although their relevance to non-homogeneous situations is questionable – see Section 5. PROFEL should be aware of these guidelines as a voluntary tool for indication on allergens.*

Recently the European Committee published a working document concerning the possible and unintentional presence in food of substances or products causing allergies or intolerances.

The reason for this working document is that:

a. many food operators use precautionary allergen labelling (PAL) such as "may contain", "may contain traces of", "made in a facility that also process ..." as a warning and to be "on the safe side"
b. this uncontrolled use results in a limited choice in food supply for allergic consumers
c. although not regulated there are general rules applicable for the use of PALs[1]
d. products that are contaminated with an allergen but not accompanied by PAL could be considered as unsafe
e. although member states are responsible for the enforcement in the EU a common approach on the application of PAL is lacking as there is no agreement on detection methods, risk assessment and risk management between the EU member states.

## 1. The legal basis for PAL proposal of the European Committee is Article 36 paragraph 3a of Regulation EU No. 1169/2011:

"*The Commission shall adopt implementing acts on the application of the requirements referred to in paragraph 2 of this Article to the following voluntary food information:*
a. *Information on the possible and unintentional presence in food of substances or products causing allergies or intolerances*".

## 2. Possible solutions that are proposed in the EC working document

a. determining levels of allergenic food below which precautionary warning labelling does not need to be used
b. impose on food business operators the requirement to carry out risk assessments if a product is suspected to be contaminated
c. standardise the wording of the PAL used by the food operators
d. harmonisation of detection methodologies of allergens present in foods
e. improve communication around PAL.

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[1] Article 14 Regulation (EC) No 178/2002:
paragraph 1: "food shall not be placed on the market if it is unsafe"
paragraph 4 "in determining whether any food is injurious to health, regard shall be had:
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers"

Avenue Jules Bordet 142, 1140 Brussels, Belgium- tel+ 32 2 761 16 56 - fax: + 32 2 761 16 99 - profel@kellencompany.eu - www.profel-europe.eu - VAT (BE) 878-357-665

## 3. Levels of allergenic food

Determining the levels of allergenic food and the executing of a **Risk Assessment** based on HACCP (Hazard Analysis and Critical Control Points) are the most interesting and challenging proposals for the food business operators.

Reference dose: absolute dose consumption of the allergen where an allergenic reaction is seen

Action level or thresholds: maximum dose of allergen per portion where no allergenic reaction is seen. No warning necessary

LOAEL: Lowest Observed Adverse Effect Levels. The lowest levels where allergenic reaction are seen

LOD: Limits of Detection by analysis

There are few thresholds (or action levels) legally regulated. Only sulphite[2] has a stated threshold within 1169/2011, of 10 mg/kg. There is separate legislation for the provision of information to consumers on the absence or reduced presence of gluten (828/2014), defined as 20ppm and 100ppm respectively, but nevertheless within 1169/2011 the presence of cereals containing gluten (at any level) are considered to be ~~an~~ allergens and have to be labelled accordingly.

The consequence of the absence of legal thresholds is that there is a zero tolerance for the presence of allergens. This means that every food processor, to satisfy the legal obligation to only supply 'safe' food, must carry out a risk assessment in order to identify whether unintentional contamination has taken place. If the conclusion is that the risk for unintentional contamination cannot be avoided ~~a~~ PAL is necessary.

## 4. VITAL (Voluntary Incidental Trace Allergen Labelling)

Part of the risk assessment could be the use of the VITAL system, as practised in Australia. The Allergen Bureau's VITAL (Voluntary Incidental Trace Allergen Labelling) Program is a standardised allergen risk assessment process for food.

This produces a 'labelling outcome' that summarizes the food allergens present in a food due to intentional inclusion as part of a recipe, and where food allergens, present due to cross contamination, should be included (or not) on the label in the form of the precautionary statement **'May be present: XXX'**

| **Allergen** | **reference dose (mg)** | **threshold or action limits** | | |
|---|---|---|---|---|
| | **protein VITAL 2.0** | **portions** | | |
| | | 5 gramms | 50 gramms | 250 gramms |
| | | | | |
| nuts | 0,1 | < 20 ppm | < 2 ppm | < 0,4 ppm |
| gluten containing grains | 1 | < 20 ppm | < 20 ppm | < 4 ppm |
| Egg | 0,03 | < 6 ppm | < 0,6 ppm | < 0,12 ppm |
| shell fish | 1 | < 200 ppm | < 20 ppm | < 4 ppm |
| Fish | 0,1 | < 20 ppm | < 2 ppm | < 0,4 ppm |
| Milk | 0,1 | < 20 ppm | < 2 ppm | < 0,4 ppm |

[2] Regulation No. 1169/2011 annex II

| | | | | |
|---|---|---|---|---|
| Peanut | 0,2 | < 40 ppm | < 4 ppm | < 0,8 ppm |
| Sesam | 0,2 | < 40 ppm | < 4 ppm | < 0,8 ppm |
| Soy | 1 | < 200 ppm | < 20 ppm | < 4 ppm |
| Lupine | 4 | < 800 ppm | < 80 ppm | <16 ppm |
| Mustard | 0,05 | < 10 ppm | < 1 ppm | < 0,2 ppm |

(source: VITAL 2.0)

The dose allergen per consumption where an allergenic reaction is seen is called the reference dose, and depending on the size of the portion this reference doses will vary. The smaller the portion the higher the amount of the allergen that is allowed, and vice versa.

**However, the VITAL systems only operate in products with a homogenous contamination, for example a liquid or powder. Although VITAL figures have no basis in EU law they may be used within the Risk Assessment to decide if the level of contamination identified is below the threshold and PAL therefore not required. Similarly, VITAL figures can be used in discussions with national Authorities to decide whether a product recall is required if stock has entered the distribution chain.**

**NB If the allergen is present and has another physical shape for instance grain seeds in lentils, the action levels of the VITAL system cannot be used. Other measures have to be taken such as prevention, cleaning, etc., to eliminate issues raised by the Risk Assessment and application of PAL is not normally appropriate.**

## 5. Risk Assessment

In the Food Drink Europe paper "precautionary allergen labelling (PAL): a science-based approach based on quantitative risk assessment" FDE recommends:

- *Clear: a single statement with a single meaning, easy to translate into EU languages, i.e. "my contain (allergen)"*
- *Not misleading: PAL should only be applied where a defined, appreciable risk has been identified through a quantitative risk assessment*
- *Based on relevant scientific data: VITAL 2.0 is the most fully elaborated system and has been subjected to extensive peer review and therefore offers the best prospects. It has also been recognised by several European national authorities*
- *Applicable in practice: analytical methods have limitations with regard to sensitivity and accuracy. Quantitative benchmarks (reference doses) require the development of capable protocols and methodologies*
- *In addition, consumers need to know that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process.*

In the FDE Guidance on food allergen management for food manufacturers (2013) the following steps for risk assessment are distinguished to manage potential risks from allergenic foods:

1. people (training, personal hygiene)
2. *supplier management*
3. raw materials handling
4. equipment and factory design
5. production process and manufacturing controls
6. consumer information
7. product development and change
8. document and record keeping
9. cleaning and validation
10. analytical methods and their application.

## 6. RASFF report contamination vegetables with allergens

A quick survey in the Rapid Alert System for Food and Feed (RASFF) in the period 01.01.2014 to 01.07.2016 gives the following six reports of alerts for fruit and vegetables contamination with allergens[3]. All those incidents led to a product recall from consumers.

Recalls:

1. fish and berries
2. mustard in gherkins
3. gluten in frozen grilled vegetables
4. gluten in lentils
5. fish in stuffed green olives
6. almond in olives.

## 7. Conclusions

1. there has been a RASFF report about contamination of lentils with gluten, but it is not known whether the contamination was by whole cereal grains (non-homogeneous) or by wheat flour (homogeneous).
2. the VITAL methodology cannot be applied as this type of contamination (lentils and grains) is not homogenous
3. prevention of contamination must be realised through risk assessment measures based on HACCP principles.
4. the results of the risk management must be used in the decision whether a PAL is necessary or not
5. it is up to the individual PROFEL members to carry out a separate Risk assessment for each product manufactured and document whether a PAL is necessary or not.

## 8. Actual information:

In the Netherlands the FNLI (umbrella association for the food industry) recently discussed with the Dutch Food Safety Authority (NVWA) the execution of the EC working document PAL. The NVWA proposes actions and procedures that practically mean that every contamination has to be labelled and even reported to the NVWA. In a following discussion the NVWA came back on this extreme point of view but they insist on the principle that a PAL or the absence of a PAL must be based on a risk assessment.

In the report “Undeclared allergens in foods, food control, analysis and risk assessment”, TemaNorden 2016 the results are illustrated of an allergen control performed by the control authorities in Denmark, Finland, Norway and Sweden in 2015. In total 351 products were checked in the categories pre-packed chocolate/candy, bakery products, ready-meals and meat and fish products. These products were analysed

[3] (search criteria: product (fruit and vegetables), type (food), classification (alert), hazard (allergen), risk decision (serious) and date (31.12.2013 – 26.07.2016)

for the allergens milk protein (casein), egg-white protein, hazelnut, peanut and gluten when these were not declared as ingredients. Some conclusions were:

- the allergenic ingredients in 10% of the controlled products were not correctly transcribed in the list of ingredients
- milk was commonly detected in products without any declaration of milk (12%)
- certain chocolate products contained milk, hazelnut and peanut in concentrations that more than 50% of the allergic consumer would react to. Allergic consumers might therefore need to avoid chocolate products with PAL for milk, hazelnut and peanut
- some food operators have no risk-based approach for investigating whether or not the allergens actually occur in their product
- 12% of the companies had not included allergens in their hazard analysis
- on 18% of the products tested, the allergens were not highlighted in the list of ingredients.

Used documents:

- VITAL 2.0 Q&A
- FDE Guidance on food allergen management for food manufacturers (January 2013)
- FDE Precautionary allergen labelling (PAL): a science-based approach based on quantitative risk assessment (FoodDrinkEurope non-paper)
- “Undeclared allergens in foods, food control, analysis and risk assessment”, TemaNorden 2016
- EC working document concerning the possible and unintentional presence in food of substances or products causing allergies or intolerances

Peter Rijnhout
VIGEF

Jeff Baxter
Technical Consultant