

Your Trainer

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Allergen Law Awareness

Clarifying Food Safety Law, its relevance to
Allergens and the Practicalities of Full
Compliance

The Legal Position – Regulatory Framework

- Criminal Liability/ Regulations:
 - Food Information for Consumers Regulation (EU FIC): Regulation (EU) No 1169/2011
 - Food Safety Act 1990
 - Food Safety and Hygiene Regulations 2013
 - EU General Food Law Regulation (EC) No. 178/2002
- Potential Civil Liability for Negligence/ Breach of Duty of Care
- Case Law – Provide indication of how courts will interpret legislation.
- Guidance Notes, Codes of Practice and Recommendations – Explain how relevant agency or enforcement body will apply legislation in practice.



- Applies directly in Member States – came into force **13 December 2014** .
- Applies to food business operators (FBOs) at all stages of the food chain, with ‘food business’ meaning any undertaking, whether for profit or not, carrying out any of the activities related to any stage of production, processing and distribution of food.
- Even FBOs not supplying directly to the consumer or to mass caterers need to ensure that their customers (i.e. business to business) have sufficient information to allow them to comply with the EU FIC.
- Provision of information to the consumer on allergens is mandatory for both pre-packed and non-prepacked foods.
- Must declare any specified allergen used in the manufacture or preparation of a food and still present in the finished product. This does not include allergens which may be present through cross-contamination.
- No specific requirements on how information must be given for non-prepacked– could be by menu, chalkboard, verbal communication.
- UK Food Information Regulations enforcement – Offence not to comply
- 14 Specified Allergens

The Legal Position – Specified Allergens under EU FIC

- **Cereals** containing Gluten - wheat, rye, barley, oats, spelt, kamut or their hybridised strains (and derivatives)
- **Crustaceans** (and derivatives)
- **Eggs** (and derivatives)
- **Fish** (and derivatives)
- **Peanuts** (and derivatives)
- **Soybeans** (and derivatives)
- **Milk** (and derivatives) except...whey used for making alcoholic distillates including ethyl alcohol of agricultural origin
- **Nuts** - almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts
- **Celery** (and derivatives)
- **Mustard Seeds** (and derivatives)
- **Sesame Seeds** (and derivatives)
- **Sulphur Dioxide and Sulphites** (concentrations more than more than 10 mg/kg or 10 mg/litre)
- **Lupin** (and derivatives)
- **Molluscs** (and derivatives)

The Legal Position – Prepacked vs Non-Prepacked

- *“**Prepacked food**’ means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; pre-packed food does not cover foods packed on the sales premises at the consumer’s request or prepacked for direct sale”*
- *“**Mass caterer**’ means any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer”*
- *“**Non- Prepacked**” - no definition in legislation – essentially anything which is not within the definition of pre-packed.*

- Mandatory particulars will include:
 - Legal name, customary name or descriptive name
 - Ingredient listing – descending order of weight
 - Net quantity declaration
 - Durability indication
 - Name or business name and address of food business operator under whose name the food is marketed, or the importer into the EU
 - Allergen information **in ingredient list** in specified format - different typeset, derivative then allergen e.g. cheese (**milk**), prawns (**crustacean**), skimmed **milk**
 - Nutrition information (mandatory from 13 December 2016)
 - Origin labelling for certain products - including for primary ingredients in all foods for which whole product origin is volunteered (e.g. apples in cider)
 - QUID (in/ next to name or in ingredient list) – Quantify ingredients that appear in name of food or are usually associated with the food, or pictures emphasising ingredients, as %.
- Various exemptions where largest surface area is less than 80cm², 25cm² and 10cm² respectively
- Alcohol over 1.2% ABV – ingredient list and nutrition information not mandatory
- Required information must be given directly on package or label attached to it.

Ingredients

Water, Carrots, Onions, Red Lentils (4.5%)
Potatoes, Cauliflower, Leeks, Peas, Cornflour, **Wheat**flour, Salt, **Cream**, Yeast Extract, Concentrated Tomato Paste, Garlic, Sugar, **Celery** Seed, Vegetable Oil (Sunflower), Herb and Spice, White Pepper, Parsley.

The Legal Position – Making Information Available (Non-Prepacked)

- Allergen information for non-prepacked food may be made available **by any means the operator chooses, including verbally.**
- **BUT** where information will be provided verbally, operator must indicate by means of:
 - Label attached to the food; or
 - On a notice, menu, ticket or label that is (1) readily discernable by (2) an intending purchaser (3) at the place where the intending purchaser chooses that food that allergen information can be obtained by asking a member of staff.
- Note these requirements also apply to foods which are packed on the sales premises at the consumer's request (e.g. deli counter), or prepacked for direct sale (e.g. sandwiches made and packed on the same premises).

- EU FIC: 'prepacked food' does not cover foods packed on the sales premises at the consumer's request or prepacked for direct sale.
- FSA Guidance 2014: This includes foods that have been packed on the same premises from which they are being sold. For a product to be considered 'prepacked for direct sale' one or more of the following can apply: It is expected that the customer is able to speak with the person who made or packed the product to ask about ingredients; and/ or Foods that could fall under this category could include meat pies made on site and sandwiches made and sold from the premises in which they are made.
- Food Information (Amendment)(England) Regulations 2019: PPDS foods must include:
 - **A list of ingredients**, which must be given directly on the package or a label attached to it; must comply with requirements for ingredients lists for prepacked foods; must be in minimum font size; must be conspicuous, visible and legible and, where appropriate, indelible; and the particulars must not be hidden, obscured or interrupted in any way by any other written or pictorial matter.
 - **Any relevant ingredient /processing aid causing allergies or intolerances** used in the manufacture or preparation of a food and still present in the finished product, in accordance with the requirements for prepacked foods; and
 - The legal name of the food.
- Remember all allergen information laws run alongside (existing) food safety laws in any event which apply to both prepacked and non-prepacked foods

FSA Draft Amended Technical Guidance on Allergen Information (Consultation closed 6 March)

- Hot food such as rotisserie chicken, displayed on counter in packaging.
- **PPDS**
- A whole cake, sliced and presented in a box to be sold by the slice
- **Not PPDS (not presented as single item)**
- Meal served on china plate in in-store cafe, prep-prepared and wrapped in cling film.
- **Not PPDS - Non-disposable tableware or crockery which remains the property of the food business is not considered to be packaging**
- Boxed salad on delicatessen counter
- **PPDS**
- A butcher who buys wholesale cuts of meat to make burgers or sausages which are prepacked to be sold on the same premises.
- **PPDS**
- A burger or boxed fried chicken wrapped when ordered
- **Not PPDS – not packed before being offered for sale**
- A wrapped burger or boxed fried chicken placed under a hot lamp
- **PPDS**

- Food Safety Act 1990:
 - Any person who sells food not of nature, substance or quality intended, is guilty of an offence.
- Food Safety and Hygiene Regulations 2013:
 - Any person who fails to comply with ‘specified EU provisions’ commits an offence.
- EU General Food Law Regulation 2002
 - Number of ‘specified provisions’, including:
 - Placing unsafe food on the market
 - Labelling, advertising and presentation of food must not mislead
 - Requirement to recall and / or withdraw food from market
 - Article 14 – food is unsafe if: injurious to health (or unfit for human consumption)
 - Regard shall be had to:
 - information provided to the consumer; and
 - the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers
- Manslaughter by gross negligence
- Health and Safety at Work etc. Act 1974

- No specific requirement for precautionary 'may contain' labelling under legislation.
- FSA Guidance:
 - If there is a risk of a food product being affected by allergen cross-contamination, the label should include one of the following statements:
 - **may contain X**
 - **not suitable for someone with X allergy**
 - Precautionary allergen labelling should only be used after a thorough risk assessment. It should only be used if the risk of allergen cross-contamination is real and cannot be removed.
- Other Detailed guidance available:
 - **Food Drink Europe (FDE) guidance on food allergen management for manufacturers:**
www.fooddrinkeurope.eu/uploads/presreleases_documents/temp_file_FINAL_Allergen_A4_web1.pdf
 - **FDf and BRC guidance on "Free-From" claims:**
https://www.fdf.org.uk/corporate_pubs/brc-free-from-guidance.pdf

- Some Bad News:
 - Strict Liability
 - Penalty: Fine / Imprisonment
 - Officer Liability
 - Maximum fine limits removed
 - Sentencing Guidelines

- Some Good News:
- Defence of Due Diligence (Food Safety Act 1990 s.21 and FSH Regs 2013 s.12)
 - General: It shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.
 - The FSA Guide on the Food Safety Act 1990 (published 2009) confirms:
 - the burden of proof lies with the person accused (as with any due diligence defence);
 - that person need only persuade the court that they exercised due diligence on the balance of probabilities;
 - ‘reasonable care’ will take account of all the facts in the case and a small business might not be required to undertake the same precautions which would be expected of one of the major retailers.

- General Guidance – Case Law:
 - Tesco Supermarkets Ltd v Natrass (1972), Lord Diplock:

“What the employer or principal can reasonably be expected to do to prevent the commission of an offence would depend upon the gravity of the injury which it is sought to prevent and the nature of the business in the course of which such offences are committed..... If considerations of costs and business practicability did not play a part in determining what employers carrying on such business could reasonably be expected to do to prevent the commission of an offence under the Act, the price to the public of the protection afforded to a minority of consumers might well be an increase in the cost of goods and services to consumers generally.”
 - Lincolnshire County Council v Safeway Stores Plc (1999):
 - Freshness control policy in force – expert witness evidence that policy had no serious inherent faults.
 - Documentary evidence produced by Safeway showed large number of shop floor items were subject to freshness checking procedures.
 - Written training manual and ‘career passports’ for each member of staff, including freshness control policy.
 - Reporting line to area office and head office if any issues identified.
 - Adequate number of random checks.
 - Immediate firm action when errors identified (including disciplinary action where appropriate and staff re-training)

“Ingredients” of Due Diligence (Cont)

- Local Authority Due Diligence Defence Guidance - Control techniques should include:
 - An assessment of the risk(s);
 - Establishing a system of reasonable safeguards;
 - Documentation of the solution;
 - Operation of the system; and
 - Review of the system.
- Application to allergen information obligations:
 - Assessing risks - suppliers/ ingredients/ communication;
 - System of safeguards - supplier agreements/ warranties, policies, electronic systems, staff training & refreshers, testing/ sampling;
 - Documentation - written training records (internal and external), signed policies, lists of ingredients, communications to staff, testing protocols, audit results;
 - Operation – ensure policies used and embedded in culture, cross-checks, internal and external audits, reporting lines to management, sanctions for non-compliance;
 - Review of system – ensure system remains fit for purpose, update to include new menu items, new ingredients, new risks, training of new staff etc.

- FSA Guidance – Allergen Information for Loose Food, includes advice on:
 - Recording information about ingredients, e.g:
 - Keep copy of ingredient information on labels of pre-packed foods used;
 - Ensure containers clearly labelled where ingredients delivered in bulk;
 - Make staff aware of where allergen information stored;
 - Keep information up-to-date e.g. if recipes change/ products substituted
 - Check deliveries – information provided with order, no omissions, same brand
 - Providing allergen information e.g.:
 - Keeping staff trained and informed;
 - Making sure allergen information accessible to all staff and updated;
 - Signposting - telling customers where they can find information;
 - Allergen menu folders – product specifications, ingredients labels, recipes
 - Dealing with severe allergic reactions

- FSA Guidance – Provision of Allergen Information for Non Pre-packed foods (2008 voluntary best practice guidance) – 3 key messages:
 - Effective communication (with customer, with suppliers and between staff)
 - Training for staff – handling allergy-related requests for information and if customer having allergic reaction
 - Accurate ingredient information – on packs, electronic specifications, head office, delivery specifications

- Prepacked Food:
 - FSA Website: Allergen Labelling for Food Manufacturers
 - FSA Food Allergen Labelling and Information: Technical Guidance
 - BRC / FDF Guidance on Allergen Labelling and Requirements in EU FIC
 - FDF Gluten Labelling Guidance
 - CIEH/ TiFSiP – Improving the Use of May Contain Labelling
 - Food Drink Europe - Guidance on Food Allergen Management for Food Manufacturers

- Murphy's Law:
 - Anything that can go wrong will go wrong.....
- Worse case scenario:
 - Suppliers change product specifications
 - Temporary / agency staff
 - Deliveries incorrect
 - Product substitutions
 - Recipe changes / dish of the day
 - Staff illness on scheduled refresher training
 - Spillages on/ loss of allergy folder
 - Malfunction of label printers
 - No IT access

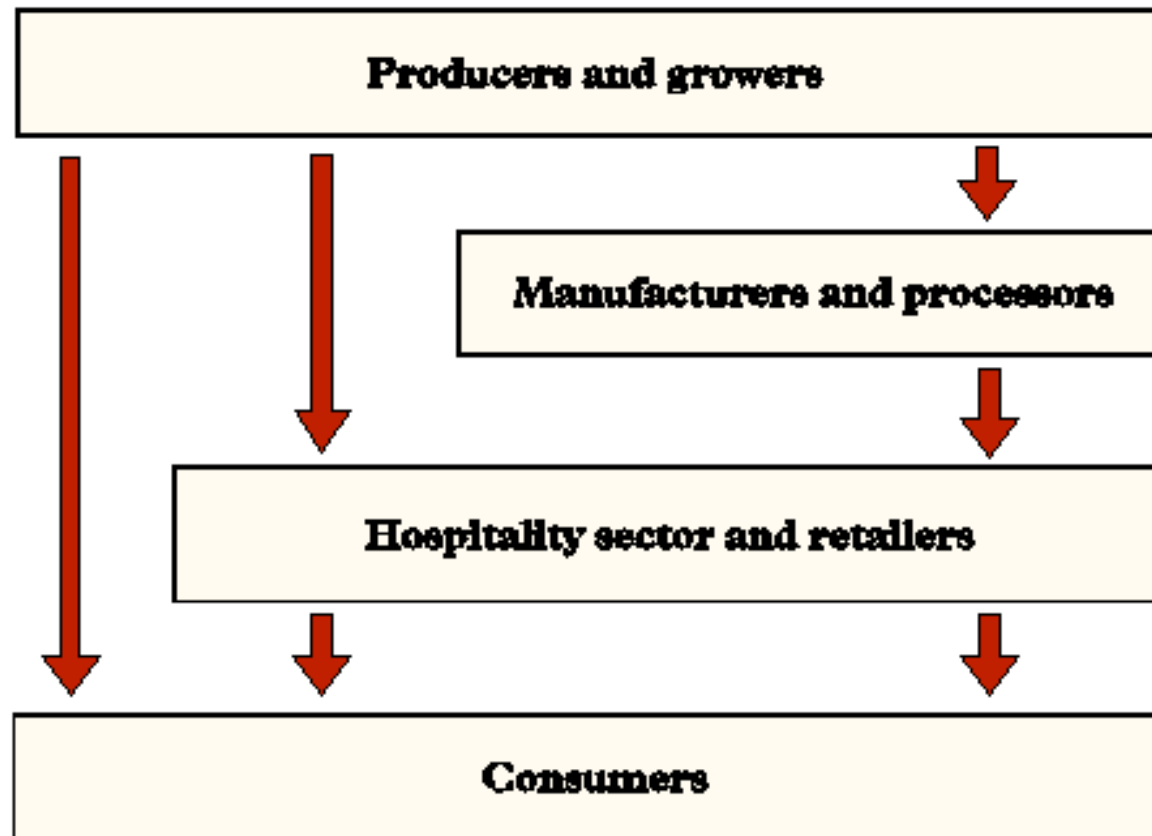




Allergen Law Awareness

Managing Communication throughout your Supply Chain:
What to Ask, When and Why

Importance of Supply Chain for Accurate Allergens



- Extra step – Third party delivery company e.g. deliveroo?

■ PRE PACKED FOODS

- name of the food
- list of ingredients
- ingredients or processing aids causing allergies or intolerances that are stated in the 14 allergens
- quantity of certain ingredients or categories of ingredients
- net quantity of the food
- date of minimum durability/ 'use by' date
- special storage conditions and/or conditions of use
- name or business name and address of the food business operator
- country of origin or place of provenance
- instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
- the alcohol strength by volume for beverages containing more than 1.2 % of alcohol, by volume
- nutritional declaration

- NON PRE-PACKAGED FOODS
 - Even FBOs not supplying directly to the consumer or to mass caterers need to ensure that their customers (i.e. business to business) have sufficient information to allow them, where appropriate, to comply with the EU FIC (Article 8(8) EU FIC).
 - Businesses are required to provide allergen and intolerance information to customers, therefore suppliers must provide this.
 - Where prepacked food is intended for supply to mass caterers for preparation, processing, splitting or cutting up, suppliers must ensure that the mandatory particulars (including allergens) shall appear on the pre-packaging or on a label attached to it, or on the commercial documents where such documents either accompany the food to which they refer or were sent before or at the same time as delivery (Article 8(7) EU FIC)
 - Food safety laws and duties of care apply.
 - If you wrap or package food as part of your business then you must:
 - use material that will not be a source of contamination for wrapping and packaging
 - store wrapping materials so they are not at risk of contamination
 - wrap and package the food in a way that avoids contamination of products
 - make sure that any containers are clean and not damaged, particularly if you use cans or glass jars
 - be able to keep the wrapping or packaging material clean

ALLERGY ALERT

12 March 2020

Miami Burger recalls Classic Miami Burgers and True Veg Burgers because of undeclared milk

Miami Burger is recalling Classic Miami Burgers and True Veg Burgers because they may contain milk which is not mentioned on their labels.

ALLERGY ALERT

7 March 2020

Food for Progress recalls Oumph! The Burger because of undeclared milk

Food for Progress is recalling Oumph! The Burger because it may contain milk which is not mentioned on the label. This means the product is a possible health risk for anyone with an allergy or intolerance to milk or milk constituents.

ALLERGY ALERT

1 March 2020

Marks & Spencer recalls M&S Chicken Bites because of undeclared egg

Marks & Spencer is recalling M&S Chicken Bites because they contain egg which is not mentioned on the label. This means the product is a possible health risk for anyone with an allergy or intolerance to egg.

What to Ask and When?

- Ingredients/ Residues:
 - Main Components
 - Food additives
 - Processing aids
 - Substitution risks
- Potential Cross-contamination:
 - Harvesting
 - Manufacturing
 - Transportation/ Storage / Packaging
- New Suppliers
- Existing Suppliers
- New/ Replacement Products / Recipe Changes
- How will Information be provided and updated?

- May contain X/ Produced in a factory which handles X/ Not suitable for X allergy sufferers etc.:
 - Prevalence of precautionary labelling
 - Inconsistency of wording
 - Reliability
- CIEH TiFSiP white paper: Improving the use of ‘may contain’ allergen statements –
 - What is the basis of the precautionary allergen statement for ‘X’?
 - Do you have X on site?
 - Was X handled on the same line?
 - Do you have products that contain X on site?
 - Do you actively monitor for the unintentional presence of X in the finished product?
 - Please explain and provide supporting evidence for the ‘may contain’ statements.
 - Do you follow the FSA Guidance on Allergen Management and Consumer Information (now contained within Food Drink Europe Guidance on Food Allergen Management best practice, or other guidance on allergen management).

- Responsibilities of Parties:
 - New products
 - Recipe changes
 - Replacements
 - Substitutions
 - Agreed notification procedure for issues
- Exclusions and Limitations of liability

Ongoing Checks

- Reporting/ tracking errors on delivery
- Investigate near misses
- Random sampling
- Horizon scanning
- Checking ingredient lists
- Third party checks

Remedies and Liabilities or Non-Compliance

- Claims under Contract
- Insurance

Questions & Answers



Local Connections Global Influence