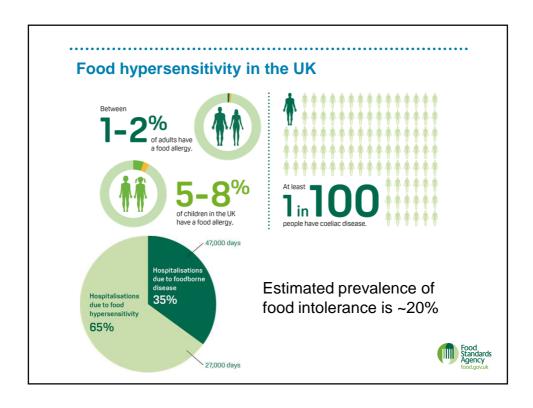




- Food is safe
- Consumers can make informed choices about what to eat



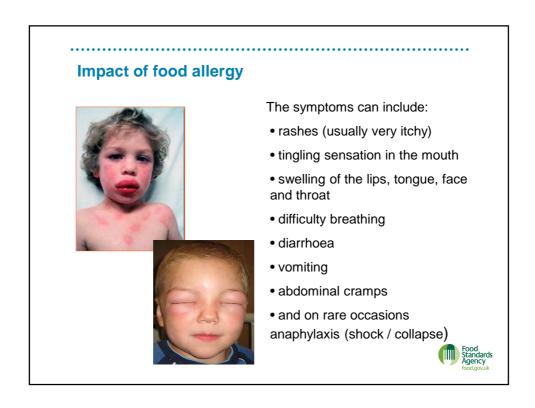


It's not a new thing...

- In 1908 First case report of anaphylactic reactions induced by food "the alimentary anaphylaxis" – Henry Hutinel
- In 1912 American pediatrician Oscar Menderson
 Schloss described scratch test as a practical diagnosis of food allergy

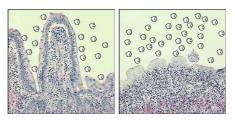






Coeliac disease

 Eating gluten leads to damage to the lining of the gut, which affects absorption of nutrients



- If diet is not controlled, this can lead to malnutrition, anaemia, osteoporosis and bowel cancer
- Need to avoid cereals containing gluten wheat (spelt and Khorasan), rye, barley and oats

Impact of food allergy - Quality of Life

Cummings et al., 2010 (Allergy, 65) FA has a detrimental affect on QoL and psychological distress (stress, depression and anxiety)

Knibb et al., 2015 (Clin Transl Allergy, 5 (Suppl 3)

- Life long condition, has significant impact on QoL of the individual and to parents of children with food allergy
- Higher QoL measures when child is older, low perceived likelihood of a severe reaction and has fewer number of allergies
- Lower QoL if child has asthma, eczema, egg allergy, history of anaphylaxis or hospitalisation due to food allergy





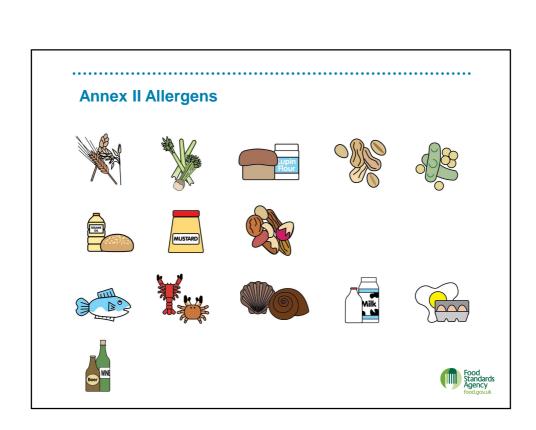
Role of Legislation

- There is no cure for food allergies or intolerances
- Dietary management is through strict avoidance diets
- Information gives a safe and informed choice
- · Legislation required as an enabler



Evolution of Allergen Labelling

- 1985 Codex Alimentarius Committee: 8 foods of public health concern
- EU labelling regulation initially didn't address the needs of allergic consumers
 - 25% rule meant that allergen information was missed out
 - 25% rule abolished allergens to be declared regardless of level
- Food Labelling Directive 2000/13/EC detailed Annex IIIa allergens and exemptions
- EU Food Information for Consumers Regulation 1169/2011 and Annex II list of allergens



Overview of allergen labelling

- Mandatory
- Declare deliberate use of allergenic ingredients or processing aids (regardless of level of inclusion)
- Voluntary
 - Unintentional presence of an allergen in food (precautionary allergen labelling)
 - Declare absence of an allergen in food (free from claims)



Allergen legislation

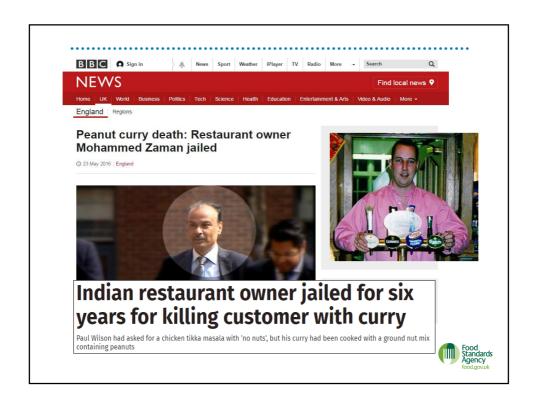
- EU Food Information for Consumers Regulation No. 1169/2011
- Allergenic ingredients information made available by food businesses
- Existing requirements for prepacked foods retained –added requirement to emphasise allergens within the ingredients list
- Introduction of extra requirement to provide allergen information for non-prepacked foods
- National provision to enable allergen information to be given orally (needs to be verifiable)



Food Allergen Legislation - Enforcement

- Enforced in UK using Food Information Regulations
 SI's (1855/2014 (England))
- Graduated approach to enforcement (informal warning to formal warning (IN's) and onto prosecution)
- Unlimited fines
- Criminal offence for breaches





Article 36 Article 2 and 3 (a) – Voluntary information

- Voluntary food information requirements:
 - Not mislead
 - To not be ambiguous or confusing
 - Where appropriate, based on relevant scientific data
- Possibility of implementing acts on the application of requirements with regard to the unintentional presence in food of substances or products causing allergies or intolerances



Precautionary allergen labelling – may contain "x"

- No specific / defined requirement in legislation
- GFL Regulation 178/2002, Art 14 (2), (3b) Food must not be unsafe...injurious to health
 - How much is too much?
- No internationally agreed approach for dealing with unintentional presence of allergens leading to inconsistencies
 - · Barriers to trade



Guidance available on PAL

Food Standards Agency (2006)

Food Drink Europe (2013)

Campden BRI Guideline 71 (2013)

Qualitative not quantitative!









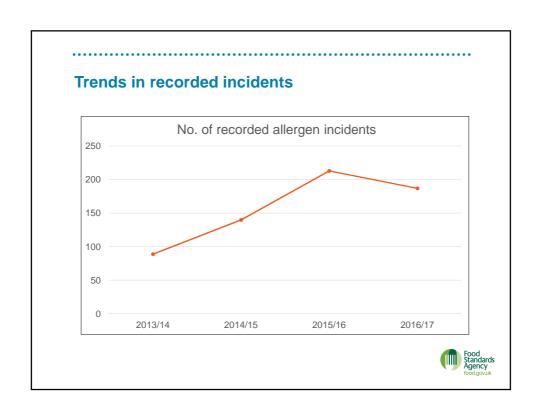


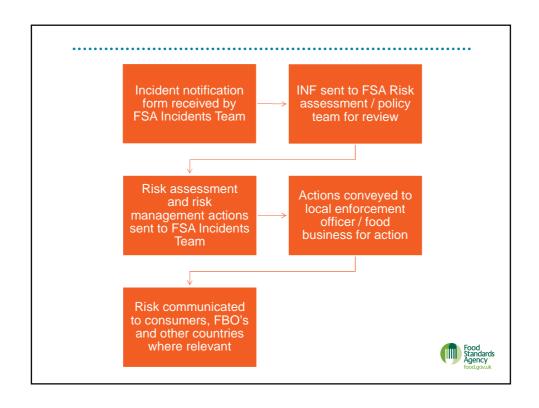
Food Allergy incidents

FSA report of Food Incidents in 2016/2017

- Not determined / other 15%
- Pathogenic microorganisms (14%)
- Residues of veterinary medicinal products (9%)
- Allergens (8%)
- Chemical contamination (other) (6%)







FSA approach to risk assessment

- · For unintentional presence of allergens
- Decision based on available information
- Risk to the consumer = Likely dose exposure
 - Amount of allergen reported (protein, total protein, DNA)
- · Portion size and/ or consumption data
- Clinical threshold data (NOAEL/LOAELs),
 reference doses...



Managing risk – a public health approach

- Risk management for public health purpose is managed on a population level
- Population data used to derive allergen reference doses
 - ED01 where 1% of population may react
 - ED05 where 5% of population may react
- Where we see a reaction we do not expect severe reactions



Cost of Recalls

- Financial impact to the food business
 - Removing product from warehouse and shelves
 - Cost of communicating the issue
 - Destroying the affected product
 - Replacing affected product with a safe product
 - Loss of profits
 - Cost of refunds

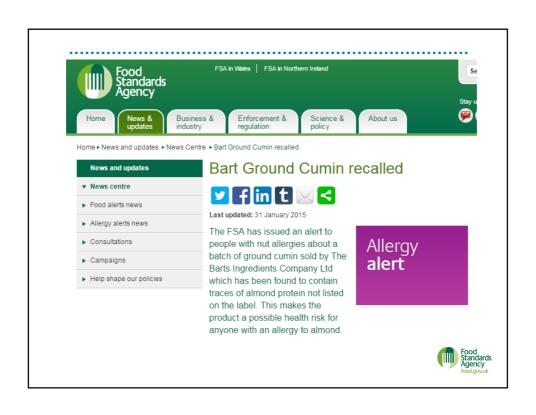


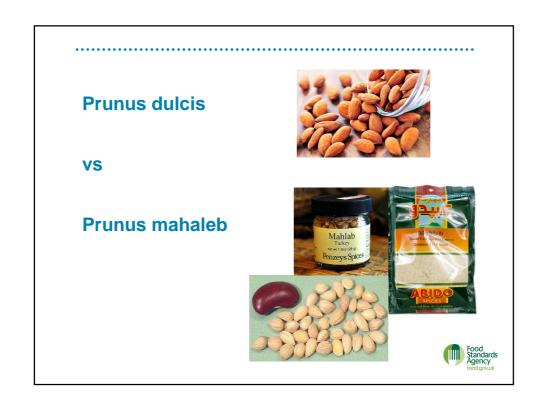


Allergen detection methods

- Must link to the hazard (protein)
- Help inform and underpin decisions on allergen management protocols, risk communication/ labelling decisions, regulatory / enforcement action
- What defines an allergenic food? e.g. DNA sequence, specific protein(s)
- Problem: cross reactivity similar looking proteins







Role of analysis in effective enforcement

- Review whether they can detect allergens at set allergen management thresholds (action levels)
- Need relevant quality control materials and/or reference materials
- Explore new technologies



An ideal world would look like

To harmonise RM approaches to PAL we need to have...

- Consistent approach to risk assessment and risk management
 - · Agree reference doses
 - · Agreed reporting units for analysis to inform risk assessment
- Established performance criteria? use any method but need to perform to set criteria
- Reference and quality control materials to ensure results are what they should be



