Food Standards Agency

food.gov.uk

REGULATORS PERSPECTIVE ON ALLERGEN MANAGEMENT IN THE FOOD INDUSTRY

IFST CONFERENCE, CAMPDEN BRI
7-8 APRIL 2011

Sue Hattersley
Head of Food Allergy Branch
UK Food Standards Agency

Food Standards Agency
food.gov.uk

Overview

- Background on European food allergen legislation
- May contain labelling
- Risk assessment of food allergy incidents
-
- Allergen management thresholds
- How this is being taken forward
- The future and next steps

Food Standards Agency
food.gov.uk

European Legislation

Food Standards Agency
food.gov.uk

Background to European food allergen legislation

Deliberate ingredients

- In Europe, Directive 2000/13/EC as amended, requires the labelling of allergenic foods when used as ingredients in pre-packed foods, whatever the level of inclusion
- Only deliberate ingredients are allowed to be listed in the ingredients list - i.e. ‘last ingredient listing’ is not allowed
- Similar provisions for the labelling of allergenic food ingredients in the USA, Australia and New Zealand (although list of allergenic foods not identical)

Food Standards Agency
food.gov.uk

EU list of allergens

Peanuts	Nuts	Milk	Soya
Mustard	Lupin	Eggs	Fish
Shellfish	Molluscs	Cereals containing gluten	Sesame
	Celery	Sulphur dioxide	

Food Standards Agency
food.gov.uk

‘May Contain’ labelling

Food Standards Agency
food.gov.uk

‘May Contain’ labelling

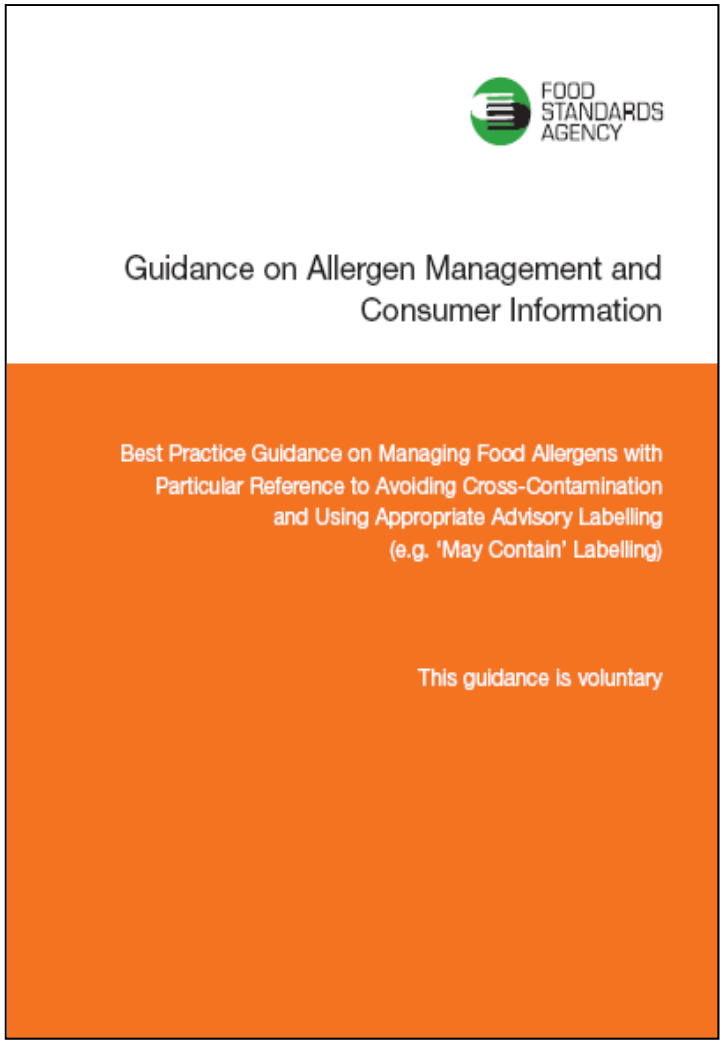
- Current legislation covers allergens as ingredients but not allergens as cross-contaminants
- Proliferation of ‘*may contain X*’ type advisory labelling
- Concerns expressed by consumers and industry:
  - over use of ‘may contain’ labelling may undermine its value
  - do different words mean different levels of risk?
  - how should businesses decide what level of risk warrants advisory labelling?
- Need for risk based approach to allergen control and allergen advisory labelling (‘*may contain X*’)

Food Standards Agency
food.gov.uk

UK FSA's Best Practice Guidance on Allergen Management and Advisory Labelling ('May Contain')

Published July 2006

Food Standards Agency
food.gov.uk



Aimed at

- medium/ large businesses
- enforcement officers
- leaflet for small and micro businesses

- Disseminated *via* industry and enforcement stakeholders involved in drafting guidance and through Agency training courses for enforcement officers
- http://www.food.gov.uk/multimedia/pdfs/maycontainguide.pdf

Food Standards Agency
food.gov.uk

Aimed at small businesses:

http://www.food.gov.uk/multimedia/pdfs/publication/allergyjamjar0109.pdf

Food Standards Agency
food.gov.uk

Main Approach of Guidance

Encourage food manufacturers and retailers to **think about risks** of allergen cross-contamination - where they occur and whether they can be reduced or eliminated

1.RISK ASSESSMENT

2.RISK MANAGEMENT

3.RISK COMMUNICATION

Only use advisory labelling after a thorough risk assessment

Food Standards Agency
food.gov.uk

Approach taken in the guidance

Qualitative – not quantitative

No allergen thresholds/management levels

- Think about risks
  - Where they arise
  - Whether they can be controlled/managed
- Decision tree approach
  - ‘Probable’ or ‘remote’
  - Worked examples

Food Standards Agency
food.gov.uk

What to put on the advisory label?

- Keep as simple as possible
- Needs to be easy to find, easy to read and easy to understand
- Two phrases recommended
  - **‘May Contain X’**
  - **‘Not suitable for someone with X allergy’**

Food Standards Agency
food.gov.uk

Risk Assessment of Food Allergy Incidents

Food Standards Agency
food.gov.uk

Risk assessment for enforcement purposes

At present, risk assessments for food allergen incidents submitted to the FSA are performed on a case by case basis.

Several factors need to be considered:

- Amount of allergen reported (allergenic protein, total protein, DNA)
- Type of food (special diet, food for children?)
- Clinical threshold data (NOAEL / LOAELs)
- Portion size
- Homogenous or heterogeneous contamination
- Amount of units in affected batch
- Distribution (local, national, international?)
- Best before / Use by Dates – remaining shelf life

Food Standards Agency
food.gov.uk

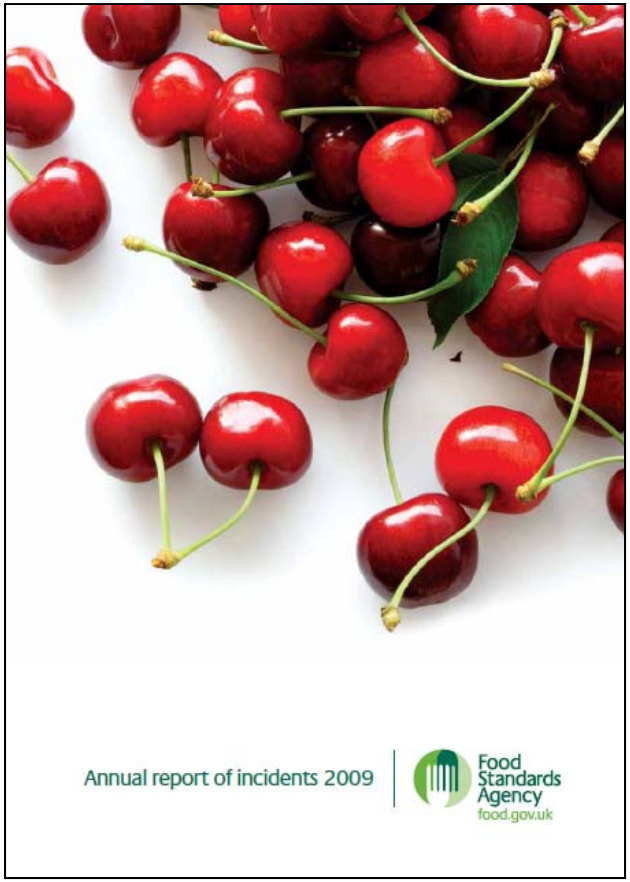
Food allergy incidents: What issues do we see?

Food Standards Agency
food.gov.uk

Number of food allergy incidents

Year	No. of incidents reported	No. of alerts issued
2008	84	59
2009	86	49

In 2009, the undeclared presence of sulphites (25) was the most common cause of food allergen incidents. This was followed by milk (16), a combination of allergens (14), cereals containing gluten (13), peanuts (12) and tree nuts (11).



Food Standards Agency
food.gov.uk

Case study 1: Undeclared milk in plain chocolate

- Routine sampling and testing found presence of milk protein in plain (dark) chocolate.
- The packaging did not indicate the presence of this allergen
- >26mg/kg of casein was reported
- Likely portion size ~45g, giving a **minimum** estimated dose of 1.2mg/casein/bar
- Clinical threshold data from food challenge studies indicate that some milk allergic consumers have reacted to these levels of milk protein
- Bar poses significant risk to some milk allergic consumers
- As the levels of casein were reported at >26mg/kg, the upper limit of contamination was not known

Food Standards Agency
food.gov.uk

The outcome was…

- Company withdrew affected product from retail sale
- Allergy support organisations were notified so they could inform their ‘at risk’ members
- The Agency issued an Allergy Alert on its website
- Affected products were over-stickered with information to inform ‘at risk’ consumers
- Food safety advice was issued and further recommendations were provided for future labelling

Food Standards Agency
food.gov.uk

Case study 2: Peanut contamination in a wafer product

- Routine local authority sampling at a wholesaler/importer
- Chocolate-covered wafers (32g) were tested for peanut, results indicated presence of peanut protein at 26.4mg/kg
- Presence of peanut not indicated on the labelling of the product in the ingredients list or as a precautionary warning
- Product was sold to small local retailers (‘corner shops’)
- Agency received information from the manufacturer that peanut was not a deliberate ingredient
- Exposure to peanut protein at a single eating occasion would be around ~0.84mg/wafer. Clinical threshold data suggested the levels found per bar may elicit subjective symptoms in very sensitive peanut allergic consumers

Food Standards Agency
food.gov.uk

The outcome was…

- None of the affected product was left at the wholesaler and identifying retailers who had bought this product to sell on would be impossible
- Small volumes of the product sold through the importer
- Agency did not issue an Allergy Alert - low levels of peanut protein per serving were considered to be unlikely to trigger a severe reaction
- Information from the wholesaler suggested that distribution may have been localised
- Agency provided advice to the manufacturer so it could re-evaluate its processes for controlling allergen cross contamination, to improve future production

Food Standards Agency
food.gov.uk

What is the way forward?

- Develop allergen management thresholds based on clinical thresholds and safety factors (where appropriate)
- Internationally agreed and accepted
- Used by industry and enforcement bodies and **understood by consumers**

Food Standards Agency
food.gov.uk

Allergen management thresholds

Food Standards Agency
food.gov.uk

What do we mean by ‘allergen management thresholds’?

- Allergen management thresholds are levels in foods below which we would not expect to elicit significant reactions in people already allergic to that food allergen

- The aim of such thresholds is to protect consumers at the public health level - not to protect every individual on every occasion against any reaction

Food Standards Agency
food.gov.uk

Can we set thresholds for different types of cross contamination?

- Yes
  - If the contamination is homogeneous throughout the product
  - If there are variable levels during the production run as long as the highest expected levels are known
- Not appropriate for discrete pieces of nut/whole seeds

Food Standards Agency
food.gov.uk

What would allergen management thresholds be used for?

Food Standards Agency
food.gov.uk

What could allergen management thresholds be used for?

- Determining levels below which cross contamination warnings/labelling does not need to be used
- Dealing with food allergy incidents
- Justifying “free-from” claims?
- Setting levels below which deliberate ingredients do not need to be labelled?

Food Standards Agency
food.gov.uk

Determination of allergen management thresholds

Food Standards Agency
food.gov.uk

What level of consumer protection should allergen management thresholds aim to provide?

- What proportion of the allergic population should thresholds aim to protect?
- Do children need greater protection? Are there ethnic differences in sensitivities to allergens? What about other health variables such as asthma control, other diseases, exercise?
- What type of reactions should thresholds aim to protect people against – severe/objective symptoms or less severe/subjective symptoms?

Food Standards Agency
food.gov.uk

Can these levels be detected/quantified?

Food Standards Agency
food.gov.uk

Development and validation of analytical methods

- Do we have robust analytical methods for the major food allergens covered by existing labelling legislation?
- Are these methods specific and sensitive?
- Are these methods rapid and suitable for use by the food industry and enforcers?
- Are these methods validated and recognised internationally?
- Do we have standard reference materials?
- Do we have agreed sampling approaches?

Food Standards Agency
food.gov.uk

How is this being taken forward?

Food Standards Agency
food.gov.uk

What is FSA doing to progress the derivation of allergen management thresholds?

Allergen management thresholds programme

- Covers clinical research, methods and utilisation of available data
- Project T07062: pooling and analysing EuroPrevall food challenge data to generate dose response curves. Testing the efficacy of commercial allergen detection kits – started Dec 2009
- Research on effect of extrinsic factors on severity and threshold of reaction – Agency's Science and Evidence Forward Plan published Feb 2011

Food Standards Agency
food.gov.uk

What else is happening?

- Collaborative work between regulators, clinicians, patients, food industry across the world
- International workshops to discuss risk assessment and tolerable risk in food allergy (Madrid 2007 and Vienna 2009 workshops)
- ILSI/FARRP/FSA Nice workshop in October 2010 - ‘Frontiers in Food Allergen Risk Assessment’
- ILSI Europe Allergy Task Force Expert Group – ‘From Thresholds to Action Levels’

Food Standards Agency
food.gov.uk

Madrid workshop: risk assessments tools

Madrid 2007 “Approaches to Risk Assessment in Food Allergy”

- Could risk assessment strategies used in toxicology be used for food allergy risk?
- Advantages and disadvantages of different risk assessment approaches
- Paper published Madsen et al., (2009) Food & Chemical Toxicology, 47, p480-89

Food Standards Agency
food.gov.uk

Vienna workshop: tolerable risk

- Vienna 2009, “Tolerable level of risk in food allergy”
- Discussed whether a tolerable level of risk could be agreed if zero risk is not feasible
- Several questions were posed to the stakeholder groups
  - *Individual vs public health level*
  - *What are we aiming to protect against?*
  - *What proportion of the population should we aim to protect?*
- Madsen *et al*., (2010) *Reg. Tox. & Pharm*., **57**, p256-65
- Second paper outlining outcome of discussions submitted for publication

Food Standards Agency
food.gov.uk

The future and next steps

Food Standards Agency
food.gov.uk

The future – what do we hope for?

- Action levels for ‘may contain’ and ‘free from’ labelling
- Clearer and simpler risk assessments
- Benefits for businesses - more certainty on application of advisory allergen labelling and better consistency between businesses
- Benefits for consumers - greater choice, more trustworthy labelling and cross-brand consistency
- Benefits for regulators - reduced need for ad hoc risk assessments, clearer guidance for enforcement

Food Standards Agency
food.gov.uk

But there are some issues we still need to resolve……

- How to use the clinical data to derive action levels
- Agreeing appropriate safety factors
- Putting action levels into practice
  - Methods (ring trials validation, harmonisation)
  - Performance of methods in different matrices and the accuracy of results
  - How to report and interpret the results

- **Informing and involving allergic consumer organisations**

Food Standards Agency
food.gov.uk

Thank you for listening – any questions?

Email: sue.hattersley@foodstandards.gsi.gov.uk

Tel: +44 (0)7276 8509

Food Standards Agency
food.gov.uk