Anaphylaxis Campaign
Supporting people with severe allergies
Corporate Member 2015



Quantitative Allergen Risk Assessment

Simon Flanagan

Senior Consultant - Food Safety Toxicology

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Customer Focused, Science Driven, Results Led

1169/2011 Voluntary Particulars

Article 36.3(a): Additional voluntary allergen labelling ("may contain" – information on the possible and unintentional presence of substances or products causing allergies or intolerances).

- Covers the requirements for voluntary food information and the implementing measures that the European Commission needs to take on the application of the requirements.
- Article 36.2 covers the general requirements that voluntary food information must meet:
  - (a) it shall not mislead the consumer, as referred to in Article 7;
  - (b) it shall not be ambiguous or confusing for the consumer; and
  - (c) it shall, where appropriate, be based on relevant scientific data.

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Hierarchy of Allergen Risks

Area of Concern	Potential Issue	Perceived Risk Level
Inaccurate consumer information (labelling / menu / verbal provision)	Undeclared allergens – Ingredient level contamination	High
Training	Skills & Awareness – potential undeclared allergen or cross-contamination	High
Management of ingredients	Undeclared allergens	High
Management of environment	Allergen cross-contamination	High
Effectiveness of cleaning	Allergen cross-contamination	Medium
Shared food contact surfaces & equipment	Allergen cross-contamination	Medium
Storage of ingredients	Allergen cross-contamination	Medium
Space constraints in preparation areas	Allergen cross-contamination	Medium
Traffic patterns	Allergen cross-contamination	Low

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Conventional Risk Assessment - Definitions (HSE 2009)

- **Risk assessment** – the **semi-quantitative** (or, in exceptional circumstances, quantitative) **estimation** of whether a **hazard** is **likely to occur** in practice; normally **expressed as a risk factor** or score by **multiplying the hazard severity score** by a **likelihood score (unlikely (score 1), likely (score 2) or very likely (score 3)**). All risk scores indicating other than low risk must be investigated and risk control/management procedures followed
- **Hazard** – a substance etc. which has the **potential to be harmful**. Hazards are very varied… The **severity of the hazard is determined by possible consequences**; for **risk assessment**, the severity of hazards is scored on a simple three point scale: **minor injury or effect (score 1), major injury or effect (score 2) or death (score 3).**
- **Risk control/risk management** – the means by which moderate or high risks identified through **risk assessment** are **eliminated** or **reduced to acceptable levels**

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Can We Apply To Allergen Risk Assessment?

- Estimation of risk – subjective
- Likelihood score – subjective
- Severity of hazard
  - Depends on the allergenic ingredient
  - Depends on sensitised individual
  - Spectrum of reaction in sensitised population from mild (1) to death (3)
- Risk management
  - Eliminated (?) or reduced to acceptable level (?)
  - Cannot completely eliminate risk
  - What is an acceptable level (no thresholds)

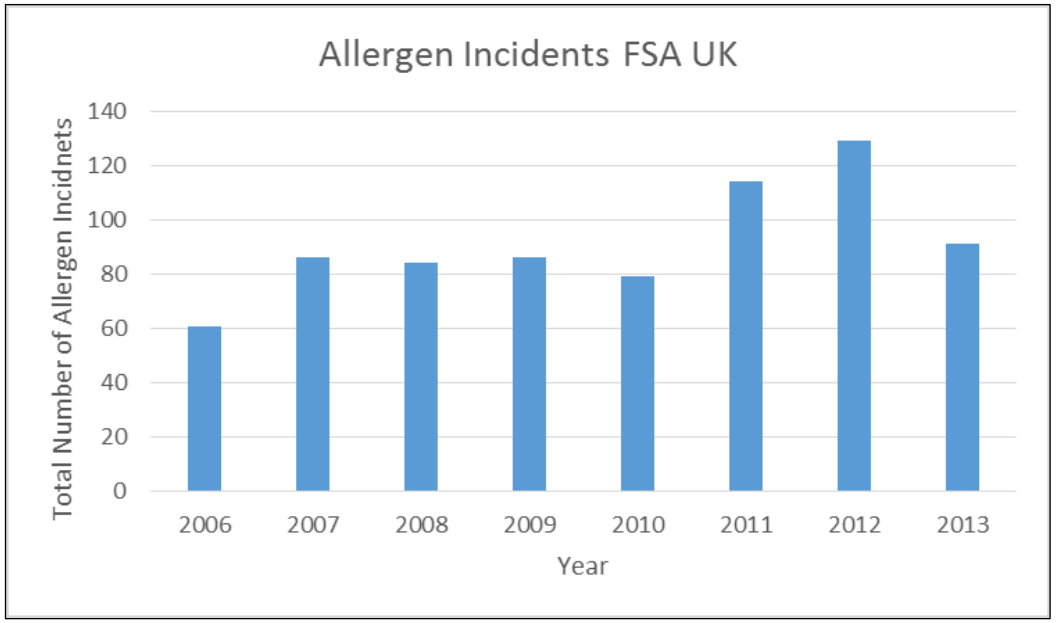
Pure HACCP Based Management Approach

- System widely used for last 10+ years
- Highly conservative – molecule hunting
- Non-standardised approach resulted in;
  - Paralysis – too difficult!
  - Risk aversion – over labelling
  - Managing all allergenic ingredients similarly
  - Inappropriate levels of testing
  - Inconsistent assessment of supply chain risk
  - Increase in recalls/withdrawals



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FSA Allergen Incidents

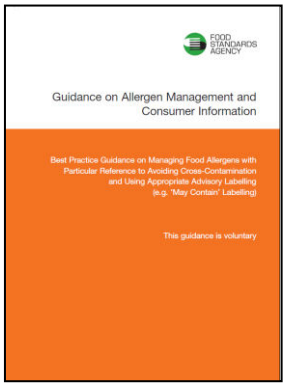


Common root cause 2008-2011	Improvements needed
Inadequate training	Capability - allergen awareness/management
Packaging errors	Label management systems
Incorrect use of ingredients	Traceability and allergen visibility

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So How Do We Move Forward?

- RSSL approach – Quantitative Risk Assessment Toolkit
- Targeted risk assessments incorporating hazard characterisation
- Evolution of 2006 FSA guidelines
- Three-tier allergen mapping
- Assessment of risks arising from the following factors
  - Process flow
  - Environmental
  - Production
  - People
- Rank risk probability against characterised hazard
- Output drives allergen management or labelling



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Allergen Mapping Level 1 Ingredient Matrix

	Milk	Egg	Cereals	Soya	Sesame	Peanut	Tree Nuts	Lupin	Celery	Mustard	Fish	Crustaceans	Molluscs	Sulphites
Bread Rolls	No	No	Yes (wheat)	Yes	No	No	No	No	No	No	No	No	No	No
Butter	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No
Chicken Stock	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No
Cloves	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Cous cous	No	No	Yes (wheat)	No	No	No	No	No	No	No	No	No	No	No
Flavour Vanilla	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Mayonaise	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No
Mustard Seeds	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No
Soya Oil	No	No	No	No (EFSA exempt)	No	No	No	No	No	No	No	No	No	No
Tinned tomatoes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Vegetable Oil	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Whey Powder	Yes (whey)	No	No	No	No	No	No	No	No	No	No	No	No	No
Worcestershire Sauce	No	No	Yes (barley malt vinegar)	Yes (soya sauce)	No	No	No	No	No	No	Yes (anchovy)	No	No	No

Can choose to add an extra layer about possible cross contact from suppliers

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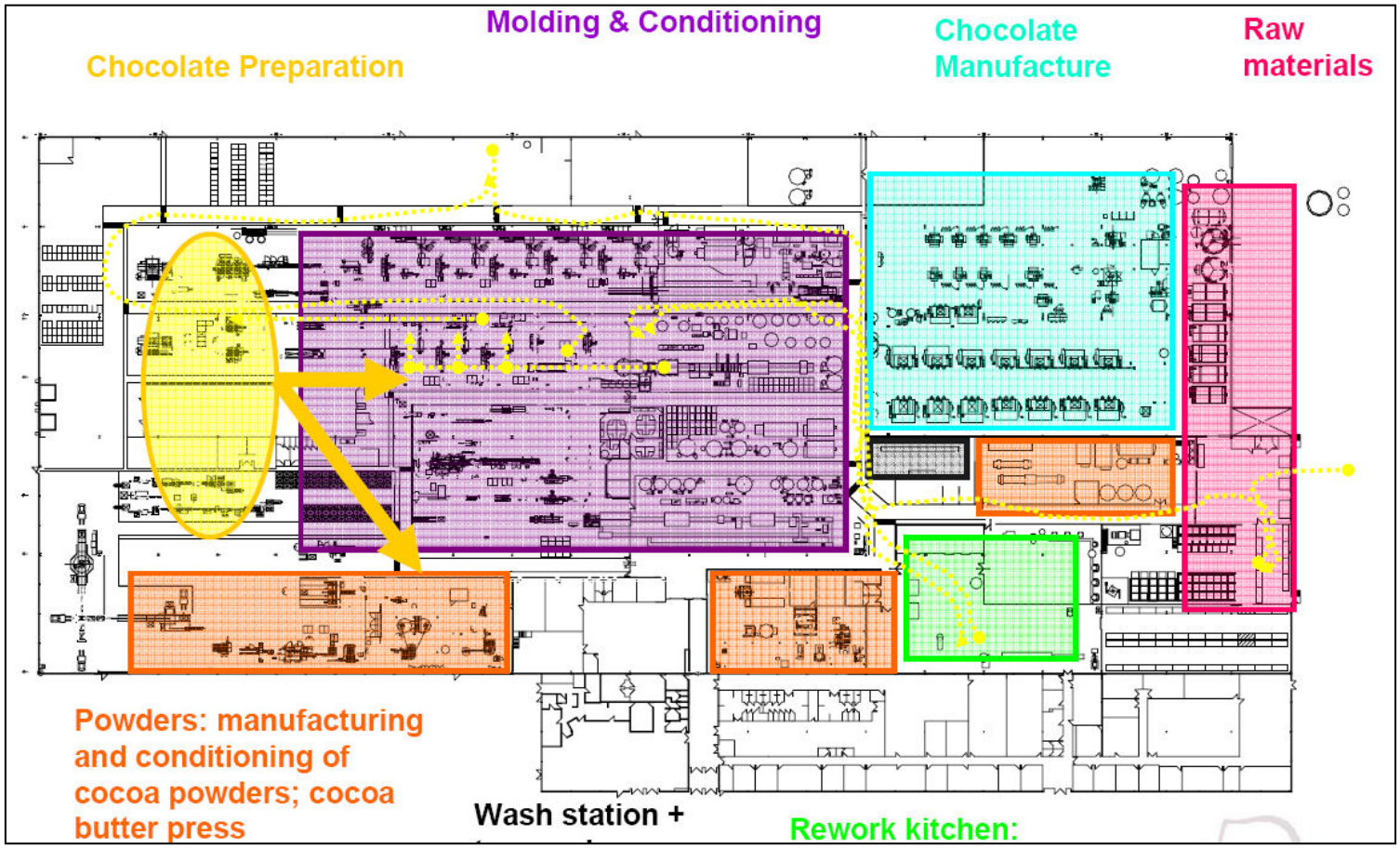
Allergen Mapping Level 2 – Recipe Matrix

	Milk	Egg	Cereals	Soya	Sesame	Peanut	Tree Nuts	Lupin	Celery	Mustard	Fish	Crustaceans	Molluscs	Sulphites
Beef Stroganoff	Yes (cream and butter)								Yes (celery stalk)	Yes (Dijon)				
Chicken and Prawn Curry		Yes (noodle)	Yes (Wheat Noodle)	Yes (fish sauce - soya sauce)							Yes (anchovy fish sauce)	Yes (prawn)		
Chicken Curry	Yes (cream)		Yes (Wheat Noodle)								Yes (anchovy fish sauce)			
Paella											Yes (monkfish)	Yes (prawn)	Yes (squid, clams, mussles)	
Singapore Stir Fry		Yes (Egg)		Yes (soya sauce)	Yes (oil)		Yes (cashew)							

Best practice to state the form of the allergen

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Allergen Mapping Level 3



Process Flow



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Environmental



Production





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People



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Probable Versus Remote





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Hazard Characterisation (1) Allergen Biochemistry

- True allergens = always proteins
- Most allergens incredibly stable molecular structures
- Some resistant to processing
  - Heat treatment
  - Mechanical
  - Fermentation
  - Some rendered 'more' allergenic



- Biochemistry (and matrix) influence cleaning interventions

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Calculation Of Hazard Score

- Use available numerical data to estimate severity of hazard
- Potency score (derived from threshold studies)
- Allergenic protein content (%)
- Physical form score
  - Measure of dilution potential through processing
  - Liquid, powder, particulate, highly processed etc.
- Amount consumer may be exposed to
- **Reliable tool for risk assessment**

Calculation of Hazard Score

Hazard Score = Potency Score x Allergenic Protein Concentration x Physical Form x Amount consumer may be exposed to

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Hazard Ratings And Associated Actions

Hazard Score	Allergen Hazard Rating	Associated Action
0 – 1,000	Low	• Record as low allergenic potential in risk assessment • This may not warrant further action however existing controls (GMPs/CCPs) must be sufficient to minimise the risk of gross contamination. Visual inspection / assessment should be suitable for validation / verification purposes • **LOW PRIORITY**
1,001 – 20,000	Medium	• Record as medium allergenic potential in risk assessment • This will warrant validation of existing controls (GMPs/CCPs) to ascertain if they are sufficient to minimise the risk of contamination. This will require validation (visual and/or analytical) & estimation of level of allergen carry-over should also be undertaken. • **MEDIUM PRIORITY**
> 20,000	High	• Record as high allergenic potential in risk assessment • This will always warrant validation of existing controls (GMPs/CCPs) to ascertain if they are sufficient to minimise the risk of contamination. This will require validation (visual and analytical) & estimation of level of allergen carry-over should also be undertaken. • **HIGH PRIORITY**

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Output From Risk Assessment

				Allergens present in area	Allergens disregarded due to being common to all products from area	Area	Chocolate custard room								
			Milk	✓											
			Gluten			Team	QA Team								
			Eggs	✓											
			Soya	✓	✓	Date	01/01/2014								
Area	**Process step**	**Allergen in question**	**Material or component containing allergen**	**Hazard**	**Probable or Remote**	**Rationale**	**Potency score (5, 50)**	**Physical Form score (10, 20, 50)**	**Protein conc score**	**Amount likely to cross contaminate**	**Hazard total**	**Hazard rating (high, med, low)**	**Controls in place**	**Controls needed to be put in place**	**Is advisory labelling needed?**
Defrost	General defrost	Egg	Egg custard	Cross contamination from tote bins to rice mix	P	Tote bins may not be washed between uses	50	10	2.92	20	29200	High	Wash after use if moving from egg to non egg mix to a cleaning SOP and sign off by quality	Need to validate the cleaning	**Yes** because validation has shown not to be consistent
Store	Ambient store	Milk	Mixes containing chocolate	Temperature probes used on milk and non milk mixes	P	Same temp probe used within area	50	20	0.3	10	3000	Medium	Alcohol wipes on probe after use	Need to validate the cleaning	**No** because validation demonstrates cleaning of temperature probes is effective

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Control Measures

- Identify existing control measures
  - Are they sufficient at reducing or eliminating the risk?
  - Control must be validated
  - If not sufficient, can they be improved?
  - Re-validate
- Examples of controls
  - Planned production scheduling
  - Physical barriers
  - Dedicated equipment, lines and storage
  - Cleaning
  - Training

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Summary

- Regulatory and Standards Expect Risk assessment
- Risk from Intentional and Unintentional presence
- Start your risk assessment with allergen mapping
- Determine probability of occurrence
- Identify risk and characterise associated hazard
- Next Step - Validation of Controls

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