‘Taking the Risk out of Allergen Risk Assessment’.

Practical Tools and Techniques for Successful Allergen Control.

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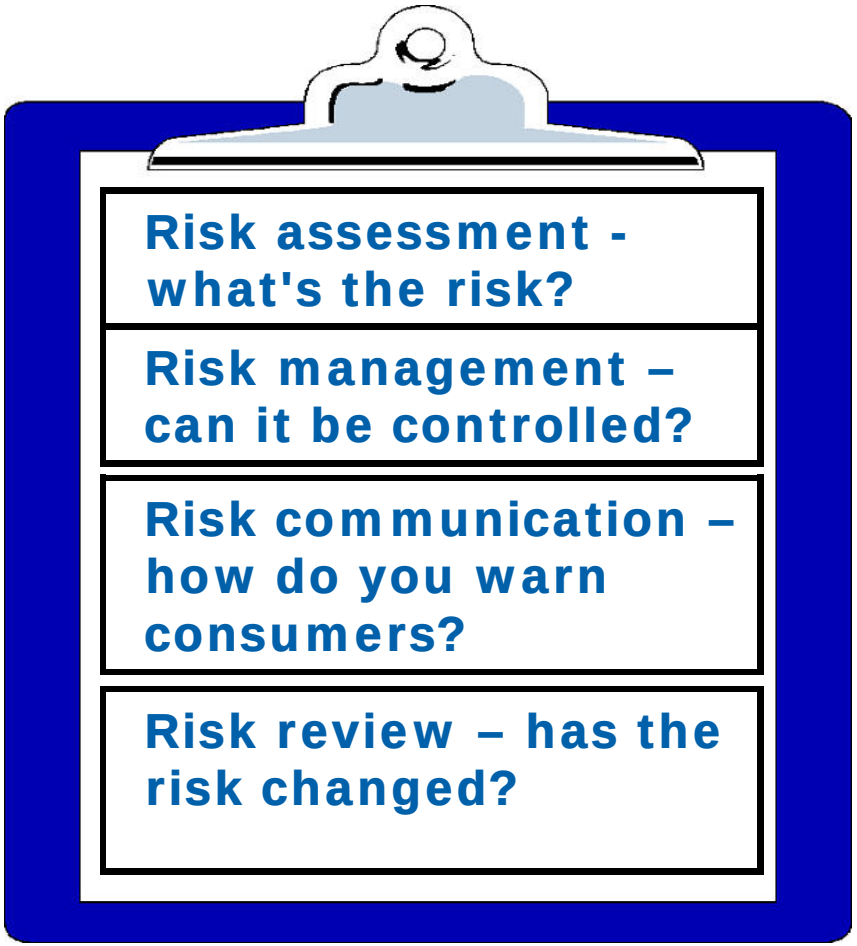
Customer Focused, Science Driven, Results Led

Overview

- Risk assessment – what does this mean?
- HACCP & allergen management
- Factory risk assessments – dos and don'ts
- Considerations in hazard characterisation
- Quantifying risk through validation
- From risk assessment to allergen control plan

Principles of Risk Analysis
FSA Orange Guide - FSA 2006



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Terminology (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

Current challenges facing Industry and Regulators

- Improvements needed in
  - Label management systems
  - Traceability and allergen visibility
  - Capability - allergen awareness/management
- Guidance needed on
  - Standardised risk assessments -
  - Translation of guidance to different sectors
  - Action levels
  - Distinction between trace level and ingredient level contamination
  - Basis for enforcement activity
  - Analytical methodology

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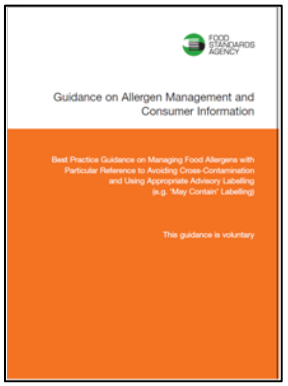
So how do we move forward?

- Standardisation is imperative
- Targeted risk assessments incorporating hazard characterization
- Evolution of 2006 FSA guidelines
- Three-tier allergen mapping
- Assessment of risks arising from the following factors
  - Process
  - Environmental
  - Production
  - People
- Rank risk probability against characterised hazard
- Output forms basis of allergen control plan



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Process

Area of Site/Process Step under Consideration	Area of Concern for Potential Allergen Cross Contact	Probability	Rationale
Process flow examples			
Ingredient Receipt	Contamination from allergenic materials during offloading from delivery vehicle and transfer to storage due to damaged packaging		
Ingredient Storage	Contamination from allergenic material due to damage to packaging during storage		
Ingredient Weighing	Dust generated from powder dispensing		
Ingredient Weighing	Ingredient will come into direct contact with equipment and utensils.		

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Environmental

Environmental factors examples			
Warehouse	Contamination of stored products due to air extract into warehouse		
Maintenance	Contamination from engineers tools – not dedicated to line		

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Production

Production related activities examples			
Waste Handling	Uncovered waste receptacle moved through production facility		
Labelling control	Wrong labels used on the line		

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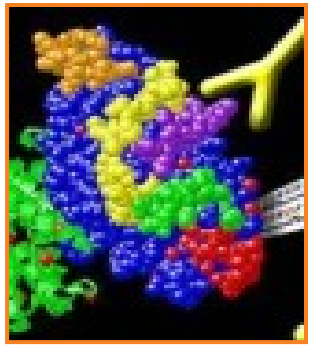
People

People related activities examples			
Hygiene	Staff moving between different lines without washing hands		
Maintenance	Maintenance teams tools identified a source of allergen cross contact		

Hazard Characterisation Allergen Biochemistry

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



- Biochemistry (and matrix) influences effectiveness of different cleaning methods

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Hazard Assessment – Consider:

- Physicochemical nature of the allergen
- Associated protein level
- Heterogeneous or homogeneous
- Concentration in recipe
- Potential for aerosol / dust generation
- Existing barriers to restrict spread of allergen
- Level of processing allergenic material undergone
- Configuration of equipment and ease of cleaning

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Calculation of Hazard Rating

- Use **available** numerical data to estimate severity of hazard

1. Potency score (derived from threshold studies)
2. Allergenic protein content (%)
3. Physical form score – measure of dilution potential through various stages of processing
   - Liquid, powder, viscous paste, particulate, etc.

- Not exact science – enables prioritisation of hazards & guides management of risk

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Validation of control measures

- Validation - quantifies otherwise subjective (qualitative) assessment
  - Fundamental part of the Hazard Analysis and Critical Control Points (HACCP)
  - ISO 22000 & PAS 220 standards require formal validation of CCPs and PRPs

Output from Risk Assessment

Area of Site/Process Step under Consideration	Area of Concern for Potential Allergen Cross Contact	Probability	Rationale	Allergen & Hazard rating	Is advisory labelling needed?
Ingredient Storage	Contamination from allergenic material due to damage to packaging during storage	Remote	Handling of this ingredient by people is minimal during storage	Milk – Med Soya – Low Almond - High	No – probability of contamination remote. Existing control measures sufficient to minimise risk
Ingredient Weighing	Dust generated from powder dispensing	Probable	Ingredient is exposed during storage	Milk – Med Wheat - Low	No – risk minimised by modifying procedure and improving local extraction at dispensing unit

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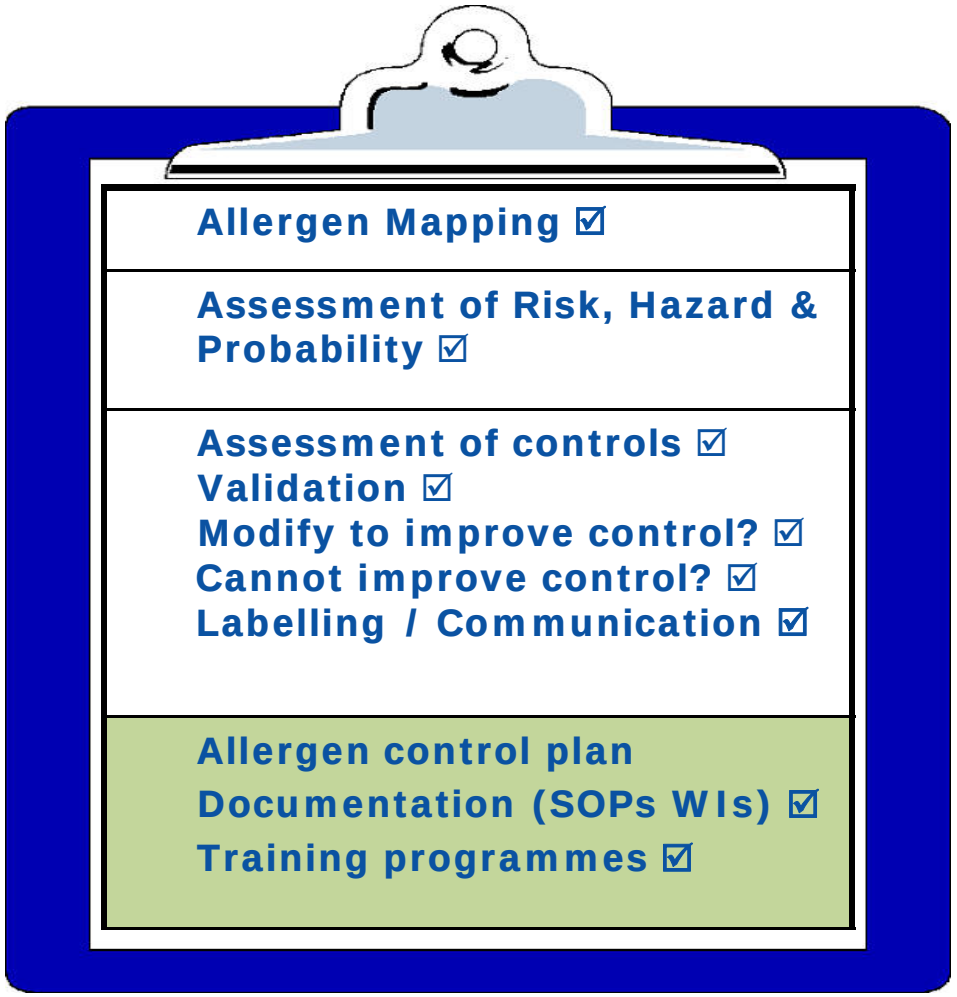
Risk Assessment to Allergen Management



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Allergen Management Plan

- Allergens as ingredients
  - Intentional presence – all allergens in recipe appear on the label

- Allergens as contaminants
  - Unintentional presence
  - Process to manage risk (or)
  - Process to communicate risk through advisory labelling

- Intrinsically linked with GMPs

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Scope of your Plan

- Raw materials (ingredients)
- Change control
- NPD
- Environment, equipment and process design
- Production scheduling, segregation
- Labelling and packaging
- Rework
- Cleaning
- Training

Ensure that its documented and keep it simple

Allergen Labelling Controls

- Wrong labels account for 75% recalls
- Wrong product in wrong package (cross-packing)
- Ingredients do not match up with ‘contains’ alert box
- ‘May-contains’ statement wrong

Practical Labelling Control for Packaging

- Considerations necessary for effective label control
  - Label copy approval against formulation
  - Verification of incoming labels against approved label copy
  - Processes for issue of correct label to packaging
  - Line clearance on product changeover
  - Line checks on correct label use

- Procedures for managing label changes
  - Introduction of new/reformulated products
  - Introduction of redesigned packaging

- Confirmation of correct legible coding/traceability information

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Training and Communication

- Vital for all personnel to be aware of the issues associated with allergens
- Include contractors, visitors etc.
- Education, training and communication is necessary, including ‘refresher’ and ‘update’ information
- Suitable signage may be used to remind personnel of importance of care and compliance with requirements
- Colour-coding - colour blindness

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Labelling for unintentional presence

- Precautionary / Advisory / Alibi / May-Contain (traces!!) labelling???

- To quote the FSA
  - "advisory labelling should only be used when, following a thorough risk assessment, there is a demonstrable and significant risk of allergen cross-contamination"

- Not a substitute for poor GMP

- So how do you communicate the risk?

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Somewhat risk averse???

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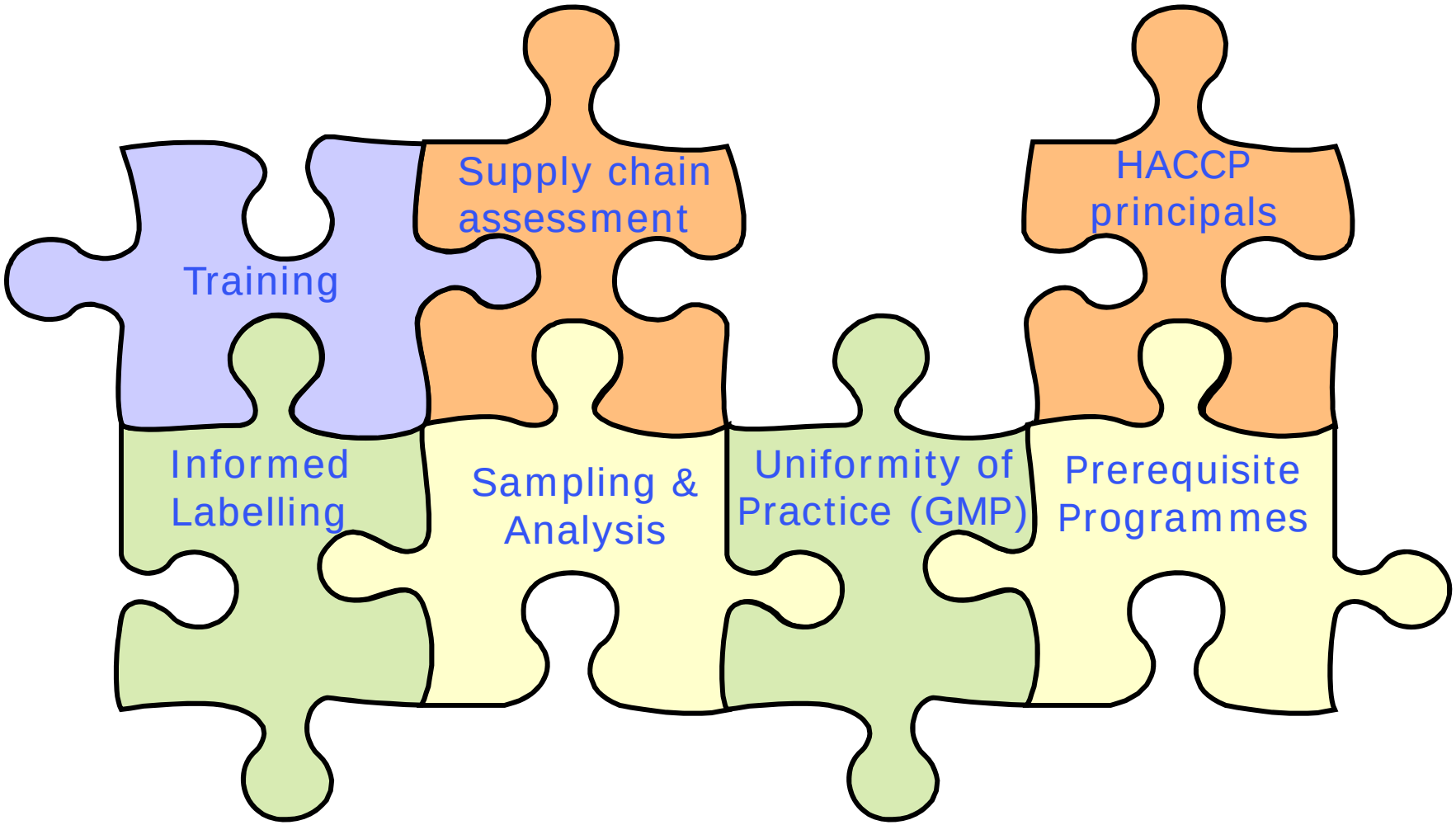
Effective Allergen Control



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Summary

- Start your risk assessment with allergen mapping
- Identify risk and characterise associated hazard
- Use validation to test your controls
- Use output to develop allergen control plan
- Allergen management must be bespoke to your site
- Keep it simple or it won't work & integrate ACP with existing food safety programme

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Thank you for your Attention

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