A Vision for Food Allergen Management

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Food Allergen Management

- Food allergy is of global and growing importance to public health
  - 17 million consumers in Europe suffer from food allergies
  - Affects consumers quality of life (mainly children)
  - Makes demands on health service resources

- Consumer health protection lies with avoidance of products containing the food to which they are allergic

- Minimising risk from allergenic foods is a shared responsibility across stakeholders
  - Healthcare professionals providing relevant diagnoses and dietary advice
  - Food chain operators providing accurate risk communication advice
  - Governments providing a protective consistent regulatory framework
  - Patients actively avoiding potential risks
A Vision for Food Allergen Management

Evolution from hazard-based approach to a risk-based approach

Increased certainty and reduced risk
- Consumer confidence in food choices
  - Active risk-avoidance behaviour
  - Harmonised international approach

- Allergens critical to public health identified using scientific criteria
- Best practice HACCP-based risk management against action level targets
- Validated capable analytical methods
- Clear, consistent food declarations relevant to allergen risk status
- Education on risk categories of products relevant to diagnoses
- Harmonised enforcement against public health guidance values

Effective public health protection for allergic consumers
- Physical, mental and social
- Preventive, rather than curative aspects of health
- Population-level, rather than individual-level health issues
A Vision for Food Allergen Management
Inter-dependent stakeholders can realize a common vision

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Critical Allergens of Public Health Importance

- Although >160 foods have been identified as able to provoke IgE-mediated allergic reactions, only a small number are responsible for the majority of the food allergy public health burden.

- Critical allergenic foods which require public health protective risk management measures can now be objectively identified using explicit scientific criteria.

- Public health measures pertinent to local needs and prioritised allergen risk management:
  - Consideration of an allergenic food’s potency, severity and prevalence, evaluated together in a weight-of-evidence approach.
Aim is to effectively protect the public health of sensitive consumers from adverse allergic reactions

Allergen action levels guide risk management decision-making

- Defining when to use precautionary warnings of unintentional presence, e.g. utilising a reference dose based on the ED01, protecting at least 99% of people allergic to the particular food from any objective reaction and minimizing probability of any serious reaction occurring in the remaining 1%.
- Defining “free from” allergen claims
- Defining levels below which intentionally present allergenic ingredients do not need to be labelled
- Guiding incident risk assessments and enforcement activities

Note: Considerations of homogeneity and production run variability need to be over-laid, and quantitative action levels not appropriate for discrete pieces e.g. nuts / whole seeds
Best practice HACCP-based risk management

Effective risk management of food allergens requires careful consideration of allergen presence

- Intentional from the recipe
- Unintentional through unavoidable cross-contamination

Integrated into good manufacturing practices (GMP), across all stages of food production from ‘farm to fork’, for each individual food operator site

- Primary food processing - seed, planting, harvesting, storage, transport
- Secondary food processing - raw materials, handling, storage, measuring, mixing, cooking, cooling, re-work, packaging, transport

Quantitative action levels deliver consistency

- Business to business declarations of foodstuff allergen status
- Use of precautionary warnings
- Enforcement expectations and actions
Best practice HACCP-based Risk Management
Key Elements

- **HACCP analysis** – are critical allergens present in the food product and/or in the handling environment?
  - Intentional presence is identified and declared
  - Likelihood and quantitative extent of unintentional (cross-contact) presence is assessed

- **Risk management** – how to control and assure finished product allergen status?
  - Segregation – storage, handling, packing - through cleaning, scheduling and planning
  - Capability of quantitative control below action levels – monitoring, validation, verification

- **Risk communication** – how to identify product allergen status?
  - Product identification and traceability
  - Clear declarations of intentional and unintentional allergen presence
Food Product Allergen Risk Categories
Accurate and consistent statements of allergen status vs. composition

<table>
<thead>
<tr>
<th>ALLERGEN STATUS</th>
<th>“FREE FROM”</th>
<th>“SUITABLE FOR”</th>
<th>“NOT SUITABLE FOR”</th>
<th>“UNFIT / UNSAFE”</th>
</tr>
</thead>
<tbody>
<tr>
<td>PUBLIC HEALTH OUTCOME</td>
<td>Not even mild reactions in the vast majority of highly sensitive allergic individuals</td>
<td>No objective reactions in the vast majority of allergic individuals</td>
<td>No severe reactions in the vast majority of allergic individuals</td>
<td>Expect severe reactions in the vast majority of allergic individuals</td>
</tr>
</tbody>
</table>

MANAGEMENT PARAMETER

| Allergen absent to a high degree of analytical confidence, special measures to ensure absence of specific allergen | Allergen management control well-managed within GMP, and cross-contact below action levels | Allergen management controls well-managed within GMP, with unavoidable traces above action levels present despite efforts | Allergen management controls and GMP NOT well-managed |

AMOUNT OF ALLERGENIC PROTEIN

lower —> higher

Manufacturing facility “IN CONTROL”

Cross-contact Action Level

Manufacturing facility “OUT OF CONTROL”

(Taken from Ward et al, Trends in Food Science and Technology 21 (12), 619-625 (2010))
Analytical capability needed to support use of quantitative action levels

Reliable quantitative detection of allergens in food
- Do we have robust analytical methods for the major food allergens covered by existing labelling legislation?
- Are these methods specific and sensitive relative to the proposed action levels?
- 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?

Reliable and relevant quantitative detection of allergens in food
- For critical allergens of public health importance
- Accurate and precise across food matrices vs. defined action levels
- Rapid and cost-effective
Clear, consistent food declarations relevant to allergen risk status

Consumer need appropriate and accurate risk communication of allergenic potential to permit sound judgments about avoiding foods

Without consistent risk communication practices

- Confusion
- Diminished trust in food labels
- Devalued impact of warnings
- Risk taking!

Clear, consistent and reliable food allergen risk communication

- Common simple descriptors for allergenic foods
- Relative to allergy diagnoses
- Meaningful and consistent statements of foodstuff allergen risk category
- Cross-brand common approaches
- Available on-line, on-pack and in retail/catering
Education on risk categories of product relevant to diagnoses

- Healthcare professionals unfamiliar with allergenic foods, their labelling requirements and food processing practices
  - Sharing of up-to-date scientific findings
  - Best practice care plans
  - Knowledge of allergenic foods and their likely sources
  - Knowledge of food product risk categories and their suitability for patients

- Improved and accessible tools to guide dietary advice by clinicians, dieticians and other health professionals
  - Specific allergen avoidance advice relative to diagnoses, including explanation of cross-reacting allergens, food product risk categories
  - Balanced diets, alternatives, recipes
  - Best practice inclusive care plans e.g. “school has a care plan, supervision, training / awareness and a policy on self-management, close parental support and the support of all other parents and pupils”
Education on risk categories of product relevant to diagnoses

- Consumer struggle to interpret food labels
  - Interpreting technical labelling terms requires specialist knowledge
  - Knowledge of food products and their likely composition needed
  - Inconsistent practices in use of precautionary warnings are confusing
  - Text small and hidden
  - Lack of reliable informed knowledge at source

- Education for patients, their families, carers and communities to allow recognition of distinct risk categories of product
  - Sources of allergens in different foods, e.g. Tofu is made from soya, French bread using lupin flour
  - Common terms used to describe allergenic foods e.g. groundnut = peanut
  - Guide to finding and interpreting ingredients declarations
  - Guide to interpreting food product risk categories vs. diagnoses e.g. “free from” claims are allergen specific, not suitable for anyone with any allergy
Harmonised enforcement cross-jurisdictions against public health guidance values

- **Regulatory controls can provide public health protection**
  - Mandatory ingredient declarations for critical allergens
  - Expectation that allergens managed as a recognised hazard through Good Manufacturing Practices and HACCP-based risk management systems

- **Absence of guidance on agreed limits for allergenic food residues**
  - Increasing use of (ever lower) analytical limits of detection for risk management decision-making, rather than public health protection criteria
  - Ad hoc management and practices including a degree of subjectivity from risk managers when dealing risk from undeclared allergens found in food
  - Significantly different approaches between jurisdictions

- **Consistent risk analysis against quantitative action levels**
  - Transparent health-based guidance values based on latest science
  - Guidance on action levels and their use defined
  - Consistency in inspection, enforcement and public health measures
Stakeholders Mutual Responsibilities

Effective food allergen risk management is a shared chain of responsibility
- Healthcare professionals
- Regulators / Public health authorities
- Food Industry
- Allergic consumers and their representatives

We need proactive aligned engagement of all stakeholders
- Access to latest scientific knowledge
- Education of all stakeholders and the wider public
- Best practice sharing
- Clear communication of risk status of food
- Consistent risk analysis against quantitative action levels
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Healthcare Professional
Consumer
Food Industry
Retail / Catering
Academia
Regulator
A Vision for Food Allergen Management

- Consistent use of quantitative health-based guidance values for optimal allergen risk management
- Inter-dependent stakeholders can realize a common vision
- A global opportunity for public health protection

Now…..

What needs to be done? By whom? When? Where?