Food Allergens

Concepts, Control, Management and Risk Assessment in Southern Africa

Dr Harris Steinman
Disclosures / Conflict of Interest

- Allergy Society of South Africa representative on FLAG
- FLAG (Food Legislative Advisory Group)
- Food & Allergy Consulting & Testing Services
- **Phadia**
  - now Thermo Fisher Scientific
  - Member: GMO Act subcommittee: Directorate Genetic Resources. Department of Agriculture Forestry & Fisheries
Origins

- Expert Technical Consultation on “Hidden” Food Allergens
- Joint FAO/WHO Expert Consultation (Food and Agriculture Organization of the United Nations/World Health Organisation.
- Rome, Italy, 13-14 November 1995
Consequences

- Regulatory environment
- Thresholds
- Manufacturing processes
- Labelling
- Education
Concepts

Diagram of a Bacterium

- Chromosome
- Cytoplasm
- Cell wall
- Plasmid
- Pilus
- Flagellum
- Cell membrane
- Capsule

Types of Bacteria:
- Coccos (spherical)
- Coccobacillus (oblong)
- Vibrio (comma-shaped)
- Bacillus (rod-shaped)
- Spirillum (spiral)
- Spirochete (spiral with a single helix)

F•A•C•T•S
Food & Allergy Consulting & Testing Services
Case Report – March 2014

• Sesame allergic 30-year-old
• From SA travelled to Israel
• Fish served with tahini at restaurant
• Within minutes had allergic reaction
• Attempt to resuscitate
• Remained in a coma for a couple of days before passing away
Food: A Warehouse

- Protein
- Carbohydrate
- Fat
- Fibre
- Minerals
- Water
- Organic compounds
- Chemicals
- Preservatives
- Additives
- Pesticides
Adverse Reactions to Food

Toxic

Non Toxic

Psychosomatic
## Food Toxins

<table>
<thead>
<tr>
<th>Type</th>
<th>Example</th>
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</thead>
<tbody>
<tr>
<td>Cyanogenic glycosides</td>
<td>Kernels of almonds, apricots, cassava</td>
</tr>
<tr>
<td>Fungal Aflatoxins toxins</td>
<td>Peanuts etc</td>
</tr>
<tr>
<td>Trichothecenes</td>
<td>Wheat</td>
</tr>
<tr>
<td>Atropine</td>
<td>Mushroom</td>
</tr>
<tr>
<td>Ochratoxin</td>
<td>Various grains</td>
</tr>
<tr>
<td>Glucosinolates</td>
<td>Brassicaceous vegetables</td>
</tr>
<tr>
<td>Pyrrolizidine alkaloids</td>
<td>Comfrey</td>
</tr>
<tr>
<td>Haemaglutinnins</td>
<td>Beans</td>
</tr>
<tr>
<td>Solanine</td>
<td>Potatoes (raw) and related plants</td>
</tr>
<tr>
<td>Sea food toxins</td>
<td>Spoiled fish, especially scombroid fish</td>
</tr>
<tr>
<td>Tetrodotoxin</td>
<td>Puffer fish</td>
</tr>
<tr>
<td>Saxitoxins</td>
<td>Clams, oysters</td>
</tr>
<tr>
<td>Waxy sterols</td>
<td>Butterfish</td>
</tr>
</tbody>
</table>

### Additional Information
- Cyanogenic glycosides are found in almonds, apricots, and cassava.
- Fungal Aflatoxins toxins are commonly found in peanuts.
- Trichothecenes are associated with wheat.
- Atropine is found in mushrooms.
- Ochratoxin is present in various grains.
- Glucosinolates are found in brassicaceous vegetables.
- Pyrrolizidine alkaloids are present in comfrey.
- Haemaglutinnins are found in beans.
- Solanine is present in potatoes (raw) and related plants.
- Sea food toxins are associated with spoiled fish, especially scombroid fish.
- Tetrodotoxin is found in puffer fish.
- Saxitoxins are present in clams and oysters.
- Waxy sterols are found in butterfish.
Adverse Reactions to Food

Toxic

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Psychosomatic
Adverse Reactions to Food

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Psychosomatically

Immune Mediated
Food Allergy

IgE

Non-IgE

Non Immune Mediated
Food Intolerance

Enzymatic

Pharmacological

Undefined
Adverse Reactions to Food

Non Toxic

Immune Mediated
Food Allergy

IgE
Non-IgE

Non Immune Mediated
Food Intolerance

Enzymatic
Pharmacological

Undefined
Adverse Reactions to Food

Non Toxic

Immune Mediated
Food Allergy
- IgE
  - Acute Wheat allergy
  - Mixed Coeliac disease
- Non-IgE
  - Delayed Delayed Wheat allergy

Non Immune Mediated
Food Intolerance
- Enzymatic
- Undefined
- Pharmacological

70%~30%

European Federation of Asthma and Allergy Associations - Position Paper on Adverse Reactions to Food
Milk

- Protein
- Lactose
- Other

Allergy
Enteropathy

Intolerance

Toxins
Allergy
What are allergens?

Most allergens are low-molecular weight proteins or glycoproteins.

Affected by proteases, heat, denaturants, allowing these foods to resist degradation during food preparation and digestion.
Milk Allergens

**Caseins 80%**
- alpha s1
- Alpha s2
- beta
- kappa

**Whey 20%**
- α lactalbumin (ALA)
- β lactoglobulin (BLG)
- bovine serum albumin (BSA)

**Lactoferrin (LF)**
**Immunoglobulins**
- β 2-microglobulin
- Transferrin
Heat Treatment II

- Can create new allergenic epitopes
- Can destroy existing epitopes
- Peanut – increase approx 90 fold
- Hazelnut – decrease approx 100 fold
  - trace proteins still affected about 30% of highly allergic patients
What does an allergic reaction look like?
Anaphylaxis

Food-related allergic reactions are the leading cause of anaphylactic reactions treated in the emergency department, accounting for approximately 30,000 emergency department visits each year, and 150-200 deaths.
Sulphur Dioxide / Sulphites

- Sodium sulphite
- Potassium sulphite
- Sodium bisulphite
- Potassium bisulphite
- Sodium metabisulphite
- Potassium metabisulphite
- Sulphur dioxide
Risk Assessment

❖ Regulators:
  ▪ Degree of allergen risk

❖ Manufacturing / Food industry
  ▪ Allergen risk assessment:
  ▪ Identification of hazard and activities able to increase the probability of that hazard occurring (risk factors)
Risk Assessment

- Regulators:
  - Prevalence of food allergy
  - ‘Major’ allergens
  - Dose Threshold
Prevalence

• Childhood food allergy in the USA
• Data for 38,480 children
• Food allergy prevalence 8.0%
• Children with food allergy:
  – 38.7% history of severe reactions
  – 30.4% had multiple food allergies.
• Peanut (25.2%), milk (21.1%), shellfish (17.2%)

CDC Study Finds 3 Million U.S. Children have Food or Digestive Allergies

The number of young people who had a food or digestive allergy increased 18 percent between 1997 and 2007, according to a new report by the Centers for Disease Control and Prevention.

From 2004 to 2006, there were approximately 9,537 hospital discharges per year.
Which foods are major allergens?

Major Food Allergens

- Peanut: 90%
- Tree nut: 90%
- Milk: 90%
- Egg: 90%
- Soy: 90%
- Fish: 90%
- Shellfish: 90%
- Wheat: 90%

10% Hundreds of others
Common Food Allergens

- Cow’s Milk
- Egg
- Soy
- Wheat
- Peanut
- Tree nuts
- Fish
- Shellfish
- Mustard
- Celery
- Sesame seed
- Lupine
- Kiwi
## Common Food Allergens

<table>
<thead>
<tr>
<th>Australia</th>
<th>France</th>
<th>Israel</th>
<th>Italy</th>
<th>Japan</th>
<th>Singapore</th>
<th>Spain</th>
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<tbody>
<tr>
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<td>Egg</td>
<td>Egg</td>
<td>Fish</td>
<td>Egg</td>
<td>Bird's nest</td>
<td>Egg</td>
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<tr>
<td>Milk</td>
<td>Peanut</td>
<td>Milk</td>
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<td>Milk</td>
<td>Seafood</td>
<td>Fish</td>
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<td>Milk</td>
<td>Milk</td>
<td>Nuts</td>
<td>Milk</td>
<td>Egg</td>
<td>Milk</td>
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<tr>
<td>Nuts</td>
<td>Mustard</td>
<td>Sesame</td>
<td>Nuts</td>
<td>Sesame</td>
<td>Seafood</td>
<td>Peach</td>
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<tr>
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<td>Cod</td>
<td>Peanut</td>
<td>Egg</td>
<td>Nuts</td>
<td>Wheat</td>
<td>Nuts</td>
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<td>Hazelnut</td>
<td>Soy</td>
<td>Mustard</td>
<td>Cod</td>
<td>Snacks</td>
<td>Lentil</td>
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<td>Kiwi</td>
<td>Nuts</td>
<td>Egg</td>
<td>Hazelnut</td>
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<td>Peanut</td>
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<td>Fish</td>
<td>Wheat</td>
<td>Strawberry</td>
<td>Fruit</td>
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<td>Chick pea</td>
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<td></td>
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<td>Vegetables</td>
<td></td>
<td>Snacks</td>
<td></td>
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<tr>
<td></td>
<td></td>
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<td>Goat milk</td>
<td></td>
<td>Beans</td>
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</table>
### Summary of Published LOAELs

<table>
<thead>
<tr>
<th>Food</th>
<th>LOAEL (mg protein)</th>
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<tbody>
<tr>
<td>Egg</td>
<td>0.13 to 1.0</td>
</tr>
<tr>
<td>Peanut</td>
<td>0.25 to 10</td>
</tr>
<tr>
<td>Milk</td>
<td>0.36 to 3.6</td>
</tr>
<tr>
<td>Tree Nuts</td>
<td>0.02 to 7.5</td>
</tr>
<tr>
<td>Soy</td>
<td>88 to 522</td>
</tr>
<tr>
<td>Fish</td>
<td>1 to 100</td>
</tr>
</tbody>
</table>

* LOAEL = Lowest Observed Adverse Effect
Prevalence of Coeliac disease

- 1 in 100 diagnosed with Celiac Disease in UK
- Celiac disease is linked to multiple affections including osteoporosis and cancer

Table 1: Prevalence of CD in Europe compared to Middle East population based on serological screenings.8-17

<table>
<thead>
<tr>
<th>Europe</th>
<th>Prevalence</th>
<th>Asia</th>
<th>Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>1:106</td>
<td>Iran</td>
<td>1:166</td>
</tr>
<tr>
<td>Czech</td>
<td>1:218</td>
<td>Israel</td>
<td>1:157</td>
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<tr>
<td>Norway</td>
<td>1:262</td>
<td>Syria</td>
<td>1:5:100</td>
</tr>
<tr>
<td>Portugal</td>
<td>1:134</td>
<td>Turkey</td>
<td>1:87</td>
</tr>
<tr>
<td>Sweden</td>
<td>1:190</td>
<td>Anatolian adults</td>
<td>1:100</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1:198</td>
<td>Kuwait (Chronic diarrhea)</td>
<td>1:18</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1:100</td>
<td>Saudi Arabia (Type 1 diabetes)</td>
<td>12:100</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1:132</td>
<td>Japan</td>
<td>1:20,000</td>
</tr>
<tr>
<td>Spain</td>
<td>1:118</td>
<td>India</td>
<td>1:500-1:20,000</td>
</tr>
</tbody>
</table>

Wheat Allergy vs Coeliac Disease

- Mediated by immune system
- **Proteins** e.g., gliadin, albumin

<table>
<thead>
<tr>
<th>Can have?</th>
<th>Wheat Allergy</th>
<th>Celiac Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wheat</td>
<td>✗</td>
<td>✗</td>
</tr>
<tr>
<td>Rye</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Barley</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Oats</td>
<td>✓</td>
<td>5%</td>
</tr>
<tr>
<td>Corn</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Rice</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

- Mediated by immune system but NOT ALLERGY
- **Proteins** - gluten
- Still an adverse reaction to food!
Gluten dose

- 10 mg in 500 g of food = 20 ppm

- 10 mg gluten is ingested in 1/250th of a slice of bread containing 2.5 g gluten

Consumer survey indicated that 30% of the people interviewed reported that they or a family member had an allergy to a food product.

22% avoided particular foods on the mere possibility that the food may contain an allergen.

Hidden Allergens

1. Contamination
2. Misleading labels
3. Specific application ingredients
4. "Ingredient switching"
5. Similar labels - dissimilar formulations
6. Labelling regulation loopholes
7. Uncommon terms

Risk Assessment

- Manufacturing / Food industry
  - Where are allergens stored?
  - How are allergens stored?
  - How are allergens handled?
  - Storage of raw materials and finished products?
  - Verified and validated cleaning regimes?
  - Are there dedicated manufacturing lines?
  - How easy is cleaning of equipment?
  - Risk of cross-contamination?
Food Allergen Risk Management: The Challenge

Protecting allergic consumers while

- Minimising the effects on their quality of life
- Maintaining economic operation of food manufacturing
Purpose of food labelling regulations?

• **Primary function** – to inform about true nature of food & provide details of ingredients which they contain

• **Practical viewpoint** – law protects allergic/intolerant individual by requiring information, not elimination

• **Level playing field** - for manufacturers
Control - Management of Allergens

- Education
- Legislation
- Manufacturing practices – ACP/HACCP
- Risk Communication (labelling)
Allergen risk management
- a shared responsibility

**Regulators**
- Balance interests of stakeholders
- Uphold the rules (compliance)

**Health professionals**
- Diagnose and advise patients

**Food Industry**
- Labels allergens
- Manages cross-contamination

**Allergic patients**
- Care in food choices
## International allergen labeling requirements

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>European Union</th>
<th>Australia-New Zealand</th>
<th>Canada</th>
<th>Japan</th>
<th>South Africa</th>
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<tbody>
<tr>
<td>Cow's milk</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Hen's egg</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Wheat</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Soy</td>
<td>Yes</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
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<tr>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Yes</td>
<td>No</td>
<td>No</td>
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<td>No</td>
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</tbody>
</table>

• Allergen-relevant articles within Regulation (EU) 1169/2011 are:
  – Article 9.1(c): Mandatory particulars
  – Article 21: Labelling of certain substances of products causing allergies or intolerances
  – Article 36.3(a): Additional voluntary allergen labelling (‘may contain’)
  – Article 44.1(a) and 44.2: Allergen labelling of non-prepacked foods
  – Annex II: List of substances or products causing allergies or intolerances
European Union

What IS NOT regulated

- Free from
- May contain
- Health claim «Convenient for allergic»

No rule
South African Labeling Regulations

Foodstuffs, Cosmetics and Disinfectants Act, Act 54 of 1972
Regulations relating to Labelling & Advertising
of Foodstuffs (R. 146/2010)
Central Government Regulations

- **Department of Health**
  - Health Act 61 of 2003
  - Hygiene Regulations – R918
  - Food Cosmetics and Disinfectants Act
    - Others including HACCP, Liquor, Salt, Sweeteners, etc

- **Department of Agriculture**
  - Product standards and labelling dairy, fruit, grains etc

- **Department of Trade and Industry**
  - Trade Metrology – weights and measures, NRCS
Extent of Declaration

Specifics:

• an ingredient
• an ingredient of
• Free-from claims
• Gluten

Compound ingredient
Additive
Processing aid
Implications of regulation:

Ingredient list:
Rice, egg, whey (milk), anchovy (fish)
lecithin (soy), spices

OR

Ingredient list:
Rice, egg, whey, anchovy,
lecithin, spices
Contains: Egg, milk, fish, soy
46(1v). the claim "gluten-free" shall not be permitted on a foodstuff

- unless the gluten level of the end-product does not exceed 20 mg/kg as analysed with the R5 Mendez Enzyme-Linked Immunosorbent Assay (ELISA) for gluten …
• Consistent approach to presentation of allergen information

Ensure clear distinction between allergens that are deliberate ingredients and those that are possible cross-contaminants.

Deliberate ingredients

Possible contaminants

Allergen advice boxes are voluntary
Precautionary label: Australia

- Avoidance of foods - depends on the wording
- 65% ignore “made in the same factory” vs 22% “may be present”
- No difference whether a history of anaphylaxis

Precautionary label: Australia

Percentage of parents of food-allergic children who reported that they would ignore a particular precautionary label, stratified by risk.

Precautionary label: Australia

• Consumers choose a gradient level of risk based on the wording of the precautionary statements
• Appear to be complacent about precautionary labelling
• Many statements now disregarded by a sizeable proportion of parents of food-allergic children, including those caring for children with a past history of anaphylaxis

Precautionary label: UK

- Substantial proportion regularly take risks purchasing food including those reporting severe reactions: current application of precautionary labelling to mitigate and communicate risk is of limited effectiveness

- Failure to read labels on every occasion highlights the importance of thinking beyond legal compliance when designing labels, for example when adding an allergen to a product that previously did not contain it.
Allergen Precautionary Labeling

Precautionary labeling provides little help to food allergic consumers if it is used promiscuously.

- Limitation of the diet
- Increased risk taking
  - Once did not react
  - Take a risk next time
- Potential reactions
Precautionary statements – NOT a substitute for GMPs

- Food Manufacturers should exercise all possible precautions in preventing contamination
  - HACCP
  - Allergen testing of products e.g. ELISA or PCR

- Due Diligence!
Should be based on thorough RISK ASSESSMENT!
• Protect consumers across board from exploitation of any kind
  - Mainly from unfair marketing practices and from hazards

• Food producers & entire supply chain exposed to civil & criminal liability in terms of CPA, various laws, regulations & by-laws

• Provides consumers with simple redress mechanism (No-fault liability)

• Big stick approach to non-compliant businesses!
  - Fine up to R 1 000 000 or 10% of turnover, whichever higher
Obstacles

1. Legislation
2. Policing
3. Enforcement
Allergen Control Program

- “Buy in” – Food Safety Culture
- Education
- Implementation
  - Ingredients & Storage
  - Equipment
  - Cross-contamination management
  - Cleaning processes
- Evaluation & Validation
- Audits
- Practical Allergen Management Workshop
Effective allergen management is a shared responsibility that requires consistency across the supply chain.
Food Standards Agency
'Annual Report of Incidents 2010'

Action taken by the Agency in 2010 included the issuing of 70 product recall and withdrawal notifications, of which 34 were Allergy Alerts.

50 % allergy!!
Food recalls

Canadian Product Recalls: 2006-2011

- Allergen: 394
- Chemical: 189
- Microbiological: 365
- Foreign objects: 131
- Other: 97
- Total: 995

http://www.inspection.gc.ca/english/corpaffr/re.../statrece.shtml
No of allergen recalls in Canada, US and Australia/New Zealand in 2007 - 2012

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<tbody>
<tr>
<td>Canada (CFIA)</td>
<td>65</td>
<td>65</td>
<td>75</td>
<td>121</td>
<td>142</td>
<td>142</td>
</tr>
<tr>
<td>US (FDA)</td>
<td>78</td>
<td>101</td>
<td>17</td>
<td>147</td>
<td>142</td>
<td>109</td>
</tr>
<tr>
<td>Australia / New Zealand (FSANZ)</td>
<td>54</td>
<td>9</td>
<td>10</td>
<td>13</td>
<td>24</td>
<td>17</td>
</tr>
</tbody>
</table>
FDA recalls:
(60% in 2013)

Leading Causes of Food Recalls
According to Recall Announcements on FDA Website

http://www.foodsafetynews.com/2013/08/undeclared-allergens-top-reason-for-second-quarter-recalls/#.UhW09tl3CeF
FDA recalls:

Table 1. Total number of yearly food product recalls, recalls due to undeclared allergens per year and recalls associated with allergic reactions

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of food product</td>
<td>276</td>
<td>213</td>
<td>254</td>
<td>242</td>
<td>259</td>
<td>393</td>
<td>1637</td>
</tr>
<tr>
<td>recalls</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undeclared allergen recalls</td>
<td>64</td>
<td>69</td>
<td>82</td>
<td>87</td>
<td>71</td>
<td>147</td>
<td>520</td>
</tr>
<tr>
<td>(% of total)</td>
<td>(23.2%)</td>
<td>(32.4%)</td>
<td>(32.3%)</td>
<td>(36%)</td>
<td>(27.4%)</td>
<td>(37.4%)</td>
<td>(31.8%)</td>
</tr>
<tr>
<td>Recalls associated with</td>
<td>10</td>
<td>11</td>
<td>17</td>
<td>11</td>
<td>7</td>
<td>8</td>
<td>64</td>
</tr>
<tr>
<td>allergic reactions</td>
<td>(15.6%)</td>
<td>(15.9%)</td>
<td>(20.7%)</td>
<td>(12.6%)</td>
<td>(9.9%)</td>
<td>(5.4%)</td>
<td>(12.3%)</td>
</tr>
<tr>
<td>(% of total allergen recalls)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* A significant increase in number of recalls is noted compared to prior years. We currently do not have an explanation for this increase.
Food allergen recalls - SA

Risk of containing nuts not listed on the label

Egg found in the “egg-free” product

Undeclared peanut present
Key Food Industry Lessons

Major company recalls

- Rework
- Inadequate cleaning of shared equipment
- Line cross-overs
- Packaging errors
- Ingredient suppliers
- Custom processors
“Muddy Waters”

• Restaurants
• Contamination: Deli’s
• Cosmetics
• DAFF laws
  Department of Agriculture, Forestry and Fisheries
• Size of manufactures
• “Accidents”
• Exemptions
• Education
“Labeling may be misleading not only because of what it says but also because of what it does not say.”
Karen Horsburgh  
Registered Dietician

Carine Davies  
Registered Dietician

Harris Steinman

Corrine Hugo  
Food Scientist

Debora v.d. Merwe  
Food Scientist (Ph.D.)

Donna Cawthorn  
Food Scientist (Ph.D.)

Shafeeqah Allie  
Administration

Comaine van Zyl  
Food Scientist

Jana du Plessis  
MSC Genetics

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